Pharmacy Prior Authorization Criteria

July 10, 2023
Statewide PDL Policies
I. Requirements for Prior Authorization of Acne Agents, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for Acne Agents, Oral must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Acne Agent, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed the Acne Agent, Oral by or in consultation with a dermatologist; AND

5. For an indication of acne, has a history of therapeutic failure of or a contraindication or an intolerance to all of the following:
   a. An oral antibiotic recommended for the treatment of acne,
   b. A topical antibiotic recommended for the treatment of acne,
   c. A topical retinoid;

   AND

6. For a non-preferred Acne Agent, Oral, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Acne Agents, Oral. See the Preferred Drug List (PDL) for the list of preferred Acne Agents, Oral at: https://papdl.com/preferred-drug-list.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Acne Agent, Oral. If the applicable guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the applicable guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a
request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

Requirements for Prior Authorization of Acne Agents, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for Acne Agents, Topical that meet any of the following conditions must be prior authorized:

1. A non-preferred Acne Agent, Topical. See the Preferred Drug List (PDL) for the list of preferred Acne Agents, Topical at: https://papdl.com/preferred-drug-list.

2. An Acne Agent, Topical that contains a topical retinoic acid derivative or azelaic acid when prescribed for a beneficiary age 21 years or older.

3. An Acne Agent, Topical with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Acne Agent, Topical, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Acne Agent, Topical, has a history of therapeutic failure, contraindication, or intolerance to the preferred Acne Agents, Topical; AND

2. For specified preferred and non-preferred Acne Agents, Topical listed in Section A.2. when prescribed for a beneficiary age 21 years or older, has a diagnosis that confirms the treatment is for a non-cosmetic indication, such as, but not limited to, acne, rosacea, or plaque psoriasis; AND

3. If a prescription for an Acne Agent, Topical is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Acne Agent, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior
authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Automated Prior Authorization**

Prior authorization of an Acne Agent, Topical will be automatically approved when one of the following is met:

1. A non-preferred Acne Agent, Topical is prescribed for a beneficiary under the age of 21 years and the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 180 days prior to the date of service that documents that the guidelines to determine medical necessity have been met. NOTE: Automated prior authorization does not apply to non-preferred Acne Agents, Topical combination products that contain an antibiotic and benzoyl peroxide.

2. An Acne Agent, Topical with the potential for cosmetic use, such as those with an active ingredient of tretinoin, adapalene, azelaic acid, or tazarotene, is prescribed for a beneficiary age 21 years or older and the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim within 180 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.
I. Requirements for Prior Authorization of Alcohol Use Disorder Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Alcohol Use Disorder Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Alcohol Use Disorder Agent. See the Preferred Drug List (PDL) for the list of preferred Alcohol Use Disorder Agents at: https://papdl.com/preferred-drug-list.

2. An Alcohol Use Disorder Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Alcohol Use Disorder Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Alcohol Use Disorder Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Alcohol Use Disorder Agents; AND

2. If a prescription for an Alcohol Use Disorder Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Alcohol Use Disorder Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Alzheimer’s Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Alzheimer’s Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Alzheimer’s Agent. See the Preferred Drug List (PDL) for the list of preferred Alzheimer’s Agents at: https://papdl.com/preferred-drug-list.

2. An Alzheimer’s Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. An acetylcholinesterase inhibitor Alzheimer’s Agent when there is a record of a recent paid claim for another acetylcholinesterase inhibitor Alzheimer’s Agent in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Alzheimer’s Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Alzheimer’s Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Alzheimer’s Agents; AND

2. For therapeutic duplication, one of the following:
   a. Is being titrated to or tapered from another acetylcholinesterase inhibitor Alzheimer’s Agent
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   AND

3. If a prescription for an Alzheimer’s Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

January 3, 2022
Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Alzheimer’s Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Analgesics, Non-Opioid Barbiturate Combinations

A. Prescriptions That Require Prior Authorization

All prescriptions for Analgesics, Non-Opioid Barbiturate Combinations must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of an Analgesic, Non-Opioid Barbiturate Combination, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Analgesic, Non-Opioid Barbiturate Combination for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; \textbf{AND}

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; \textbf{AND}

3. If age 65 years or older, \textbf{both} of the following:
   a. Received a risk assessment by the prescriber and the prescriber indicated that the benefits of the requested medication outweigh the risks for the beneficiary
   b. Has documentation of prescriber counseling regarding the potential increased risks of the requested medication;
      \textbf{AND}

4. Is not taking primidone or other medication(s) containing a barbiturate; \textbf{AND}

5. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; \textbf{AND}

6. Will not be taking the requested medication on more than three (3) days per month; \textbf{AND}

7. Has a diagnosis of headache based on the current International Headache Society Classification of Headache Disorders; \textbf{AND}

8. Has a history of trial and failure, intolerance, or contraindication of standard abortive medication based on headache classification as recommended by the most recent American Academy of Neurology, American Academy of Family Physicians, World Health Organization, or European Academy of Neurology treatment guidelines; \textbf{AND}

9. If being treated for chronic daily headache, defined as the presence of headache on 15 days or more per month for at least three (3) months, \textbf{all} of the following:
a. Has documentation of results of a physical examination and complete neurologic examination to rule out secondary causes of headache,

b. Has documentation of an evaluation for the overuse of abortive medications, including but not limited to acetaminophen, NSAIDs, triptans, butalbital, caffeine, and opioids,

c. Has documentation of prescriber counseling regarding behavioral modifications, such as cessation of caffeine and tobacco use, improved sleep hygiene, diet changes, and regular mealtimes,

d. **One** of the following:

   i. Is taking preventive drug therapy based on headache classification as recommended by the most recent American Academy of Neurology, American Academy of Family Physicians, World Health Organization, or European Academy of Neurology treatment guidelines

   ii. Has a contraindication or intolerance of standard preventive drug therapies,

   e. Has documentation of prescriber counseling regarding the potential adverse effects of Analgesics, Non-Opioid Barbiturate Combinations, including the risk of medication overuse headache, misuse, abuse, and addiction,

   f. For a beneficiary with a history of substance use disorder, has results of a recent urine drug screen (UDS) testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances;

**AND**

10. Is being treated by a prescribing provider who confirms that he/she, or the prescribing provider’s delegate, conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary’s controlled substance prescription history before prescribing the Analgesic, Non-Opioid Barbiturate Combination; **AND**

11. For a non-preferred Analgesic, Non-Opioid Barbiturate Combination, has a history of therapeutic failure, contraindication, or intolerance of the preferred Analgesic, Non-Opioid Barbiturate Combinations. See the Preferred Drug List (PDL) for the list of preferred Analgesics, Non-Opioid Barbiturate Combinations at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list); **AND**

12. If a prescription for an Analgesic, Non-Opioid Barbiturate Combination is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Analgesic, Non-Opioid Barbiturate Combination. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Analgesics, Opioid Long-Acting

A. Prescriptions That Require Prior Authorization

All prescriptions for Analgesics, Opioid Long-Acting must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Analgesic, Opioid Long-Acting, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Analgesic, Opioid Long-Acting, **one** of the following:

   a. For a non-preferred buprenorphine product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting containing buprenorphine,

   b. For a non-preferred tramadol product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting containing tramadol,

   c. For all other non-preferred Analgesics, Opioid Long-Acting, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Long-Acting

      See the Preferred Drug List for the list of preferred Analgesics, Opioid Long-Acting at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list); **AND**

2. For an Analgesic, Opioid Long-Acting when the beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol), is prescribed both prescriptions by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s); **AND**

3. **One** of the following:

   a. **One** of the following:

      i. For a beneficiary under 18 years of age, **both** of the following:

         a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services

         b) The Analgesic, Opioid Long-Acting does not contain codeine or tramadol

      ii. For a beneficiary 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services
b. **All** of the following:

i. Has documentation of pain that is **all** of the following:
   a) Caused by a medical condition,
   b) Not migraine in type,
   c) Severe,

ii. Has a history of therapeutic failure of or a contraindication or an intolerance to non-opioid analgesics (e.g., acetaminophen, NSAIDs, gabapentinoids, duloxetine, tricyclic antidepressants) appropriate for the beneficiary’s condition,

iii. Has documentation of a trial of Analgesics, Opioid Short-Acting,

iv. Is opioid-tolerant (for adults, is defined as taking at least morphine 60 mg/day, transdermal fentanyl 25 mcg/hour, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equi-analgesic dose of another opioid for one week or longer),

v. Is prescribed a dose that is appropriate based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

vi. Was assessed for potential risk of opioid misuse or use disorder by the prescribing provider,

vii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,

viii. Has results of a recent urine drug screen (UDS) testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) that is consistent with prescribed controlled substances,

ix. For a beneficiary under 18 years of age, is prescribed a medication and dose that is appropriate based on the beneficiary’s age, weight, and concurrent medical conditions and is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

**AND**

4. For therapeutic duplication, **one** of the following:

a. Is being transitioned to or from another Analgesic, Opioid Long-Acting with the intent of discontinuing one of the medications

b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

**AND**
5. If a prescription for an Analgesic, Opioid Long-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter and all of the following:

a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least one of the following:

   i. Pain is inadequately controlled at the current quantity limit
   ii. Pain is inadequately controlled by other Analgesics, Opioid Long-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,

b. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,

c. The requested dosing frequency is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a 1-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANALGESICS, OPIOID LONG-ACTING: The determination of medical necessity of a request for renewal of a prior authorization for an Analgesic, Opioid Long-Acting that was previously approved will take into account whether the beneficiary:

1. One of the following:

   a. One of the following:

      i. For a beneficiary under 18 years of age, both of the following:

         a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services
         b) The Analgesic, Opioid Long-Acting does not contain codeine or tramadol
ii. For a beneficiary 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services

b. **All** of the following:

i. Has documentation of improvement in pain control and/or level of functioning while on the requested agent,

ii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined medically necessary,

iii. Has results of a UDS testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) at least every 12 months that is consistent with prescribed controlled substances;

**AND**

2. If a prescription for an Analgesic, Opioid Long-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter and **all** of the following:

a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least one of the following:

i. Pain is inadequately controlled at the current quantity limit

ii. Pain is inadequately controlled by other Analgesics, Opioid Long-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Long-Acting,

b. There is documentation demonstrating an appropriate upward titration of or an appropriate conversion from other opioid-containing medications,

c. The requested dosing frequency is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a 1-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.
C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Analgesic, Opioid Long-Acting. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of an Analgesic, Opioid Long-Acting will be approved for up to 6 months.

E. References

1. Methadone: focus on safety. Pharmacist's Letter/Prescriber's Letter 2006; 22(9):220902


I. Requirements for Prior Authorization of Analgesics, Opioid Short-Acting

A. Prescriptions That Require Prior Authorization

Prescriptions for Analgesics, Opioid Short-Acting that meet any of the following conditions must be prior authorized:

1. A non-preferred Analgesic, Opioid Short-Acting. See the Preferred Drug List (PDL) for the list of preferred Analgesics, Opioid Short-Acting at: https://papdl.com/preferred-drug-list.

2. An Analgesic, Opioid Short-Acting with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. An Analgesic, Opioid Short-Acting when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

4. An Analgesic, Opioid Short-Acting when a beneficiary has a concurrent prescription for a buprenorphine agent with a U.S. Food and Drug Administration (FDA)-approved indication for opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol).

5. An Analgesic, Opioid Short-Acting that contains codeine or tramadol when prescribed for a beneficiary under 18 years of age.

6. An Analgesic, Opioid Short-Acting that does not contain codeine or tramadol when prescribed for a beneficiary under 18 years of age and at least one of the following:
   a. More than a 5-day supply is prescribed.
   b. The beneficiary has a history of a paid claim for an Analgesic, Opioid Short-Acting within the past 180 days.

7. An Analgesic, Opioid Short-Acting when prescribed for a beneficiary 18 years of age or older and at least one of the following:
   a. More than a 10-day supply is prescribed.
   b. The beneficiary has a history of a paid claim for an Analgesic, Opioid Short-Acting within the past 180 days.

B. Review of Documentation for Medical Necessity
In evaluating a request for prior authorization of a prescription for an Analgesic, Opioid Short-Acting, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a transmucosal fentanyl product, **all** of the following:
   a. Has a diagnosis of cancer,
   b. Is opioid-tolerant,¹
   c. Is prescribed the requested transmucosal fentanyl product by a specialist certified in pain medicine, oncology, or hospice and palliative medicine by the American Board of Medical Specialties,
   d. Has a history of a contraindication to the preferred Analgesics, Opioid Short-Acting;

   **AND**

2. For nasal butorphanol, **both** of the following:
   a. Is not opioid-tolerant¹
   b. **One** of the following:
      i. **All** of the following:
         a) Has a diagnosis of pain,
         b) Is being prescribed nasal butorphanol by a specialist certified in neurology, pain medicine, oncology, or hospice and palliative medicine by the American Board of Medical Specialties,
         c) Has a history of therapeutic failure, contraindication, or intolerance of at least 3 unrelated (i.e., different opioid ingredient) preferred Analgesics, Opioid Short-Acting (single-entity or combination products)
      ii. **All** of the following:
         a) Has a diagnosis of migraine,
         b) Is prescribed nasal butorphanol by a neurologist or headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties,
         c) Has a history of therapeutic failure, contraindication, or intolerance of all of the following abortive therapies:
            (i) Acetaminophen,
            (ii) Non-steroidal anti-inflammatory drugs (NSAIDs),
            (iii) Triptans,

¹ Opioid tolerant is defined as taking at least morphine 60 mg/day, transdermal fentanyl 25 mcg/hour, oxycodone 30 mg/day, oral hydromorphone 8 mg/day, or an equianalgesic dose of another opioid for one (1) week or longer.
(iv) Dihydroergotamine,

d) Has a history of therapeutic failure, contraindication, or intolerance of all of following preventive therapies:

(i) Anticonvulsants,
(ii) Beta blockers,
(iii) Botulinum toxin (for a diagnosis of chronic migraine only),
(iv) Calcitonin gene-related peptide inhibitors/antagonists,
(v) Calcium channel blockers,
(vi) Serotonin-norepinephrine reuptake inhibitors,
(vii) Tricyclic antidepressants;

AND

3. For a combination agent containing a barbiturate, also meets the prior authorization guidelines related to Analgesics, Non-Opioid Barbiturate Combinations; **AND**

4. For a non-preferred Analgesic, Opioid Short-Acting, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Analgesics, Opioid Short-Acting; **AND**

5. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder OR naltrexone for extended-release injectable suspension (Vivitrol), is prescribed both prescriptions by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s); **AND**

6. For therapeutic duplication, **one** of the following:

   a. Is being transitioned to or from another Analgesic, Opioid Short-Acting with the intent of discontinuing one of the medications
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   **AND**

7. **One** of the following:

   a. **One** of the following:

      i. For a beneficiary under 18 years of age, **both** of the following:

         a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services or is receiving treatment post-operatively or following a traumatic injury
b) The Analgesic, Opioid Short-Acting does not contain codeine or tramadol

ii. For a beneficiary 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services or is receiving treatment post-operatively or following a traumatic injury

b. All of the following:

i. Has documentation of pain that is all of the following:
   a) Caused by a medical condition,
   b) Not migraine in type,
   c) Moderate to severe,

ii. Has a history of therapeutic failure of or a contraindication or an intolerance to non-opioid analgesics (e.g., acetaminophen, NSAIDs, gabapentinoids, duloxetine, tricyclic antidepressants) appropriate for the beneficiary’s condition,

iii. Was assessed for potential risk of opioid misuse or use disorder by the prescribing provider,

iv. Is prescribed a dose that is appropriate based on FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

v. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,

vi. For beneficiaries who have received opioid treatment for the past 3 months, has results of a recent urine drug screen (UDS) testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) that is consistent with prescribed controlled substances,

vii. For a beneficiary under 18 years of age, is prescribed a medication and dose that is appropriate based on the beneficiary’s age, weight, and concurrent medical conditions and is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

8. If a prescription for an Analgesic, Opioid Short-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account the guidelines set forth in the Quantity Limits Chapter and both of the following:

a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least one of the following:
i. Pain is inadequately controlled at the current quantity limit
ii. Pain is inadequately controlled by other Analgesics, Opioid Short-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting

b. The beneficiary would not be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long-Acting.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a 1-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANALGESICS, OPIOID SHORT-ACTING: The determination of medical necessity of a request for renewal of a prior authorization for an Analgesic, Opioid Short-Acting that was previously approved will take into account whether the beneficiary:

1. **One** of the following:
   a. **One** of the following:
      i. For a beneficiary under 18 years of age, **both** of the following:
         a) Has a diagnosis of active cancer, sickle cell with crisis, or neonatal abstinence syndrome or is receiving palliative care or hospice services
         b) The Analgesic, Opioid Short-Acting does not contain codeine or tramadol
      ii. For a beneficiary 18 years of age or older, has a diagnosis of active cancer or sickle cell with crisis or is receiving palliative care or hospice services
   b. **All** of the following:
      i. Has documentation of improvement in pain control and/or level of functioning while on the requested agent,
      ii. Is not taking a benzodiazepine, unless the benzodiazepine or opioid is being tapered or concomitant use is determined to be medically necessary,
      iii. Has results of a UDS testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, buprenorphine, and tramadol) at least every 12 months that is consistent with prescribed controlled substances;
2. If a prescription for an Analgesic, Opioid Short-Acting is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will take into account the guidelines set forth in the Quantity Limits Chapter and both of the following:

a. An opioid analgesic at the requested dose is the most appropriate treatment option as documented by at least one of the following:

   i. Pain is inadequately controlled at the current quantity limit
   ii. Pain is inadequately controlled by other Analgesics, Opioid Short-Acting or the beneficiary has a history of a contraindication or adverse reaction to alternative Analgesics, Opioid Short-Acting

b. The beneficiary would not be more appropriately pain controlled by initiating or adjusting the dose of an Analgesic, Opioid Long-Acting.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved. When the above guidelines are not met but the beneficiary is receiving ongoing opioid therapy, a 1-month approval will be issued to avoid abrupt discontinuation while the requested information to determine medical necessity is submitted.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Analgesic, Opioid Short-Acting. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of an Analgesic, Opioid Short-Acting will be approved for up to 6 months.

E. References:


July 10, 2023


Requirements for Prior Authorization of Androgenic Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Androgenic Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Androgenic Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Androgenic Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a history of a contraindication to the prescribed medication; AND

4. For a diagnosis of hypogonadism, has clinical and laboratory findings (such as testosterone, luteinizing hormone [LH], follicle-stimulating hormone [FSH]) supporting the diagnosis; AND

5. For gender dysphoria, both of the following:
   a. Is prescribed the Androgenic Agent by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine
   b. Is prescribed the Androgenic Agent in a manner consistent with the current World Professional Association for Transgender Health standards of care for the health of transsexual, transgender, and gender nonconforming people; AND

6. For a non-preferred Androgenic Agent, has history of therapeutic failure, contraindication, or intolerance to the preferred Androgenic Agents approved or medically accepted for the beneficiary’s diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Androgenic Agents at: https://papdl.com/preferred-drug-list; AND

7. For therapeutic duplication, one of the following:
   a. Is being titrated to or tapered from a drug in the same class
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines; AND

January 5, 2021
8. If a prescription for an Androgenic Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Androgenic Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

Requirements for Prior Authorization of Angiotensin Modulators

A. Prescriptions That Require Prior Authorization

Prescriptions for Angiotensin Modulators that meet any of the following conditions must be prior authorized:

1. A non-preferred Angiotensin Modulator, including an Angiotensin Modulator in combination with HCTZ. See the Preferred Drug List (PDL) for the list of preferred Angiotensin Modulators at: https://papdl.com/preferred-drug-list.

2. An Angiotensin Modulator with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. An Angiotensin Modulator when there is a record of a recent paid claim for another Angiotensin Modulator or an Angiotensin Modulator Combination in Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Exemptions from Prior Authorization

The following are exempt from prior authorization:

1. Qbrelis (lisinopril oral solution) when prescribed for a child under 9 (nine) years of age.

2. Epaned (enalapril oral solution) when prescribed for a child under 9 (nine) years of age.

C. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Angiotensin Modulator, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For an aliskiren agent, both of the following:
   a. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature
   b. Has a documented diagnosis of uncontrolled hypertension despite treatment with the following drug classes at maximum tolerated Food and Drug Administration (FDA)-approved doses unless contraindicated: calcium channel blockers, beta blockers, diuretics, ACE inhibitors, and ARBs;

   AND

2. For all other non-preferred Angiotensin Modulators, has a history of therapeutic failure, contraindication, or intolerance of the preferred Angiotensin Modulators; AND

3. For therapeutic duplication, one of the following:
a. Is being titrated to or tapered from another Angiotensin Modulator or Angiotensin Modulator Combination
b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND

4. If a prescription for an Angiotensin Modulator is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

D. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C. above to assess the medical necessity of a prescription for an Angiotensin Modulator. If the guidelines in Section C. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

E. References

I. Requirements for Prior Authorization of Angiotensin Modulator Combinations

A. Prescriptions That Require Prior Authorization

Prescriptions for Angiotensin Modulator Combinations that meet any of the following conditions must be prior authorized:

1. A non-preferred Angiotensin Modulator Combination. See the Preferred Drug List (PDL) for the list of preferred Angiotensin Modulator Combinations at: https://papdl.com/preferred-drug-list.

2. An Angiotensin Modulator Combination with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. An agent that contains an angiotensin converting enzyme (ACE) inhibitor when there is a record of a recent paid clam for another agent that contains an ACE inhibitor or an angiotensin receptor blocker (ARB) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

4. An agent that contains an ARB when there is a record of a recent paid clam for another agent that contains an ARB or an ACE inhibitor in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

5. An agent that contains a calcium channel blocker when there is a record of a recent paid clam for another agent that contains a calcium channel blocker in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Angiotensin Modulator Combination, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Angiotensin Modulator Combination, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Angiotensin Modulator Combinations; AND

2. For therapeutic duplication, one of the following:
   a. For an ACE inhibitor, is being transitioned to another ACE inhibitor or ARB with the intent of discontinuing one of the medications,
   b. For an ARB, is being transitioned to another ARB or ACE inhibitor with the intent of discontinuing one of the medications,
   c. For a calcium channel blocker, is being transitioned to another calcium channel blocker with the intent of discontinuing one of the medications,
   d. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

January 9, 2023
3. If a prescription for an Angiotensin Modulator Combination is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Angiotensin Modulator Combination. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antianginal Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antianginal Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Antianginal Agent. See the Preferred Drug List (PDL) for the list of preferred Antianginal Agents at: https://papdl.com/preferred-drug-list.

2. An Antianginal Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antianginal Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antianginal Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antianginal Agents; **AND**

2. If a prescription for an Antianginal Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antianginal Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antibiotics, GI and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antibiotics, GI and Related Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Antibiotic, GI and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Antibiotics, GI and Related Agents at: https://papdl.com/preferred-drug-list.

2. An Antibiotic, GI and Related Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotic, GI and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antibiotic, GI and Related Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. For Dificid (fidaxomicin) for the treatment of *Clostridioides difficile* infection (CDI), one of the following:
   a. Has at least one of the following factors associated with a high risk for recurrence of CDI:
      i. Age ≥ 65 years,
      ii. Clinically severe CDI (as defined by a Zar score ≥ 2),
      iii. Is immunocompromised,
   b. Has a recurrent episode of CDI,
   c. Is prescribed Dificid (fidaxomicin) as a continuation of therapy upon inpatient discharge;
AND

5. For the treatment of travelers’ diarrhea, has a history of therapeutic failure, contraindication, or intolerance of azithromycin; **AND**

6. For the treatment of hepatic encephalopathy, has a history of therapeutic failure, contraindication, or intolerance of lactulose; **AND**

7. For the treatment of irritable bowel syndrome with diarrhea (IBS-D), is prescribed the requested medication by or in consultation with a gastroenterologist; **AND**

8. For Zinplava (bezlotoxumab), **all** of the following:

   a. Is prescribed Zinplava (bezlotoxumab) by or in consultation with a gastroenterologist or an infectious disease specialist,

   b. Has a recent stool test positive for toxigenic *Clostridioides difficile*,

   c. Has at least **one** of the following factors associated with a high risk for recurrence of CDI:
      i. Age ≥ 65 years,
      ii. Extended use of one or more systemic antibacterial drugs,
      iii. Clinically severe CDI (as defined by a Zar score ≥ 2),
      iv. At least one previous episode of CDI within the past 6 months or a documented history of at least two previous episodes of CDI,
      v. Is immunocompromised,
      vi. The presence of a hypervirulent strain of CDI bacteria (ribotypes 027, 078, or 244),

   d. Is receiving Zinplava (bezlotoxumab) in conjunction with an antibiotic regimen that is consistent with the standard of care for the treatment of CDI,

   e. Has not received a prior course of treatment with Zinplava (bezlotoxumab); **AND**

9. For all other non-preferred Antibiotics, GI and Related Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antibiotics, GI and Related Agents approved or medically accepted for the beneficiary’s diagnosis; **AND**

10. If a prescription for an Antibiotic, GI and Related Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   **NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the
professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN ANTIBIOTIC, GI AND RELATED AGENT FOR AN INDICATION OF IBS-D: The determination of medical necessity of a request for renewal of a prior authorization for an Antibiotic, GI and Related Agent for an indication of IBS-D that was previously approved will take into account whether the beneficiary:

1. Has documentation of a successful initial treatment course; AND
2. Has documented recurrence of IBS-D symptoms; AND
3. For Xifaxan (rifaximin), has not received 3 treatment courses in the beneficiary’s lifetime; AND
4. If a prescription for an Antibiotics, GI and Related Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antibiotic, GI and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Zinplava (bezlotoxumab) and Xifaxan (rifaximin) will be approved for a dose and duration of therapy consistent with FDA-approved package labeling.

E. References

Requirements for Prior Authorization of Antibiotics, Inhaled

A. Prescriptions That Require Prior Authorization

Prescriptions for Antibiotics, Inhaled that meet any of the following conditions must be prior authorized:

1. A non-preferred Antibiotic, Inhaled. See the Preferred Drug List (PDL) for the list of preferred Antibiotics, Inhaled at: https://papdl.com/preferred-drug-list.

2. An Antibiotic, Inhaled with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotic, Inhaled, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. For a non-preferred Antibiotic, Inhaled, **one** of the following:
   
a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Antibiotics, Inhaled approved for the beneficiary’s diagnosis
b. Has culture and sensitivity test results that document that only a non-preferred Antibiotic, Inhaled will be effective;

   **AND**

5. If a prescription for an Antibiotic, Inhaled is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process
Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antibiotic, Inhaled. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antibiotics, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Antibiotic, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Antibiotics, Topical at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antibiotic, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antibiotics, Topical.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antibiotic, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Anticoagulants

A. Prescriptions That Require Prior Authorization

Prescriptions for Anticoagulants that meet any of the following conditions must be prior authorized:

1. A non-preferred Anticoagulant. See the Preferred Drug List (PDL) for the list of preferred Anticoagulants at: https://papdl.com/preferred-drug-list.

2. An Anticoagulant with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm. **Exception: Enoxaparin (Lovenox) does not have a quantity limit/day supply restriction in place**

3. An oral Anticoagulant when there is a record of a recent paid claim for another oral Anticoagulant in the Department of Human Services’ (Department) Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. An injectable Anticoagulant when there is a record of a recent paid claim for another injectable Anticoagulant in the Department’s Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Anticoagulant, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Anticoagulant, has a history of therapeutic failure, contraindication, or intolerance of the preferred Anticoagulants approved or medically accepted for the beneficiary’s diagnosis or indication; AND

2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a history of a contraindication to the prescribed medication; AND

4. For therapeutic duplication, one of the following:
   a. For an oral Anticoagulant, is being titrated to or tapered from another oral Anticoagulant,
   b. For an injectable Anticoagulant, is being titrated to or tapered from another injectable Anticoagulant,
   c. Has a clinical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   AND

Last revision date: 2/18/2020
5. If a prescription for an Anticoagulant is for a quantity that exceeds the quantity limit, the
determination of whether the prescription is medically necessary will also take into account
the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the
professional judgment of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be
approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the
clinical guidelines in Section B. above to assess the medical necessity of a prescription for an
Anticoagulant. If the guidelines in Section B. are met, the reviewer will prior authorize the
prescription. If the guidelines are not met, the prior authorization request will be referred to a
physician reviewer for a medical necessity determination. Such a request for prior
authorization will be approved when, in the professional judgment of the physician reviewer,
the services are medically necessary to meet the medical needs of the beneficiary.

D. References

   March 2018.
I. Requirements for Prior Authorization of Anticonvulsants

A. Prescriptions That Require Prior Authorization

Prescriptions for Anticonvulsants that meet any of the following conditions must be prior authorized:

1. A non-preferred Anticonvulsant. See the Preferred Drug List (PDL) for the list of preferred Anticonvulsants at: https://papdl.com/preferred-drug-list.

2. An Anticonvulsant with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A prescription for clonazepam when prescribed for a beneficiary under 21 years of age.

4. A prescription for clonazepam when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

5. A prescription for a clonazepam when there is a record of 2 or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System within the past 30 days.

6. A prescription for clonazepam when a beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Anticonvulsant, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Anticonvulsant, one of the following:
   a. Has a current history (within the past 90 days) of being prescribed the same non-preferred Anticonvulsant (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)
   b. All of the following:
      i. One of the following:
         a) For a diagnosis of a seizure disorder, has a documented history of therapeutic failure of or a contraindication or an intolerance to two preferred Anticonvulsants approved or medically accepted for the beneficiary’s diagnosis (therapeutic
failure of preferred Anticonvulsants must include the generic equivalent when the
generic equivalent is designated as preferred)

b) For all other diagnoses, has a documented history of therapeutic failure of or a
contraindication or an intolerance to the preferred Anticonvulsants approved or
medically accepted for the beneficiary’s diagnosis (therapeutic failure of preferred
Anticonvulsants must include the generic equivalent when the generic equivalent
is designated as preferred),

ii. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug
Administration (FDA)-approved package labeling OR a medically accepted
indication,

iii. Is prescribed a dose that is consistent with FDA-approved package labeling,
nationally recognized compendia, or peer-reviewed medical literature,

iv. Is age-appropriate according to FDA-approved package labeling, nationally
recognized compendia, or peer-reviewed medical literature;

AND

2. For clonazepam, all of the following:

a. For a beneficiary under 21 years of age, one of the following:

i. Has a diagnosis of one of the following:

   a) Seizure disorder,
   b) Chemotherapy induced nausea and vomiting,
   c) Cerebral palsy,
   d) Spastic disorder,
   e) Dystonia,
   f) Catatonia

ii. Is receiving palliative care,

b. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for
the treatment of opioid use disorder, both of the following:

i. Is prescribed the buprenorphine agent and clonazepam by the same prescriber or, if
prescribed by different prescribers, all prescribers are aware of the other
prescription(s)

ii. Has an acute need for therapy with clonazepam,

b. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for
the treatment of opioid use disorder, both of the following:

i. Is prescribed the buprenorphine agent and clonazepam by the same prescriber or, if
prescribed by different prescribers, all prescribers are aware of the other
prescription(s)

ii. Has an acute need for therapy with clonazepam,

b. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for
the treatment of opioid use disorder, both of the following:

i. Is prescribed the buprenorphine agent and clonazepam by the same prescriber or, if
prescribed by different prescribers, all prescribers are aware of the other
prescription(s)

ii. Has an acute need for therapy with clonazepam,

b. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for
the treatment of opioid use disorder, both of the following:

i. Is prescribed the buprenorphine agent and clonazepam by the same prescriber or, if
prescribed by different prescribers, all prescribers are aware of the other
prescription(s)

ii. Has an acute need for therapy with clonazepam,
d. When there is a record of 2 or more paid claims for any benzodiazepine, both of the following:

i. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed medical literature or national treatment guidelines

ii. The multiple prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s),

e. One of the following:

i. Meets the guidelines in B.2.a.

ii. Has documentation that the prescriber or the prescriber’s delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary’s controlled substance prescription history;

AND

3. If a prescription for an Anticonvulsant is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Anticonvulsant. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Antidepressants, SSRIs
(Selective Serotonin Reuptake Inhibitors)

A. Prescriptions That Require Prior Authorization

Prescriptions for Antidepressants, SSRIs that meet any of the following conditions must be prior authorized:

1. A non-preferred Antidepressant, SSRI. See the Preferred Drug List (PDL) for the list of preferred Antidepressants, SSRIs at: https://papdl.com/preferred-drug-list.

2. An Antidepressant, SSRI with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. An Antidepressant, SSRI when there is a record of a recent paid claim for another Antidepressant, SSRI in Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antidepressant, SSRI, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antidepressant, SSRI, one of the following:
   a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Antidepressants, SSRIs
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antidepressant, SSRI;

   AND

2. For therapeutic duplication, one of the following:
   a. Is being titrated to or tapered from a drug in the same class
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   AND

3. If a prescription for an Antidepressant, SSRI is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.
NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antidepressant, SSRI. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Antidepressants, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Antidepressants, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Antidepressant, Other. See the Preferred Drug List (PDL) for the list of preferred Antidepressants, Other at: https://papdl.com/preferred-drug-list.

2. An Antidepressant, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antidepressant, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antidepressant, Other, **one** of the following:
   a. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antidepressant, Other
   b. **All** of the following:
      i. **At least two** of the following:
         a) Has a history of therapeutic failure, contraindication, or intolerance of the preferred Antidepressants, Other approved or medically accepted for the beneficiary’s diagnosis at maximally tolerated doses for a duration of ≥ 6 weeks,
         b) Has a history of therapeutic failure, contraindication, or intolerance of the Antidepressants, SSRIs approved or medically accepted for the beneficiary’s diagnosis at maximally tolerated doses for a duration of ≥ 6 weeks,
         c) Has a history of therapeutic failure, contraindication, or intolerance of augmentation therapy (e.g., lithium, antipsychotic, stimulant) in combination with an antidepressant approved or medically accepted for the beneficiary’s diagnosis at maximally tolerated doses for a duration of ≥ 6 weeks,
      ii. **Is prescribed the Antidepressant, Other for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,**
iii. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

iv. Is prescribed a dose and frequency that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

v. Does not have a history of a contraindication to the prescribed medication;

AND

2. For Spravato (esketamine), all of the following:

   a. Is prescribed Spravato (esketamine) by or in consultation with a psychiatrist,
   b. Is prescribed Spravato (esketamine) in conjunction with a therapeutic dose of an oral antidepressant,
   c. Does not have severe hepatic impairment (Child-Pugh class C);

AND

3. If a prescription for an Antidepressant, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANTIDEPRESSANTS, OTHER: The determination of medical necessity of a request for renewal of a prior authorization for an Antidepressant, Other that was previously approved will take into account whether the beneficiary:

1. For Spravato (esketamine), all of the following:

   a. Is prescribed Spravato (esketamine) by or in consultation with a psychiatrist,
   b. Is prescribed Spravato (esketamine) in conjunction with a therapeutic dose of an oral antidepressant,
   c. Has documentation of improvement in disease severity since initiating treatment,
   d. Does not have severe hepatic impairment (Child-Pugh class C);

   AND

2. If a prescription for an Antidepressant, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.
NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antidepressant, Other. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antiemetic/Antivertigo Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antiemetic/Antivertigo Agents that meet the following conditions must be prior authorized:

1. A non-preferred Antiemetic/Antivertigo Agent. See the Preferred Drug List (PDL) for the list of preferred Antiemetic/Antivertigo Agents at: https://papdl.com/preferred-drug-list.

2. An Antiemetic/Antivertigo Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A prescription for promethazine for a child under 6 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiemetic/Antivertigo Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being prescribed the Antiemetic/Antivertigo Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. For a non-preferred Antiemetic/Antivertigo Agent, one of the following:
   a. For a non-preferred oral serotonin receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred oral serotonin receptor antagonists,
   b. For a non-preferred non-oral serotonin receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-oral serotonin receptor antagonists,
   c. For a non-preferred oral neurokinin-1 receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred oral neurokinin-1 receptor antagonists,
   d. For a non-preferred non-oral neurokinin-1 receptor antagonist, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred non-oral neurokinin-1 receptor antagonists,
   e. For all other non-preferred Antiemetic/Antivertigo Agents, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiemetic/Antivertigo Agents approved or medically accepted for the beneficiary’s diagnosis;
AND

3. For promethazine for a child under 6 years of age, all of the following:
   a. Is experiencing acute episodes of nausea and/or vomiting,
   b. Is at risk for emergency department/hospital admission for dehydration,
   c. Has demonstrated therapeutic failure of or a contraindication or an intolerance to oral rehydration therapy,
   d. Has demonstrated therapeutic failure of or a contraindication or an intolerance to alternative pharmacologic treatments, such as ondansetron,
   e. Will not be taking promethazine concomitantly with a medication with respiratory depressant effects, including cough and cold medications,
   f. Has a documented evaluation for causes of persistent nausea and/or vomiting if symptoms have been present for more than one week,
   g. Does not have a history of a contraindication to the prescribed medication;

AND

4. If a prescription for an Antiemetic/Antivertigo Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antiemetic/Antivertigo Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References


I. Requirements for Prior Authorization of Antifibrotic Respiratory Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antifibrotic Respiratory Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antifibrotic Respiratory Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antifibrotic Respiratory Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Does not have a contraindication to the prescribed medication; AND

5. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); AND

6. If a current smoker, has documentation of being advised by the prescriber to stop smoking; AND

7. For a non-preferred Antifibrotic Respiratory Agent, one of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antifibrotic Respiratory Agents approved or medically accepted for the beneficiary’s indication
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antifibrotic Respiratory Agent

See the Preferred Drug List (PDL) for the list of preferred Antifibrotic Respiratory Agents at: https://papdl.com/preferred-drug-list; AND

8. If a prescription for an Antifibrotic Respiratory Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs
that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN ANTIFIBROTIC RESPIRATORY AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an Antifibrotic Respiratory Agent will take into account whether the beneficiary:

1. Based on the prescriber's assessment, is benefitting from the requested medication; **AND**
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**
3. Does not have a contraindication to the prescribed medication; **AND**
4. Is prescribed the requested medication by or in consultation with an appropriate specialist (e.g., pulmonologist, rheumatologist, etc.); **AND**
5. If a prescription for an Antifibrotic Respiratory Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antifibrotic Respiratory Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
D. References


I. Requirements for Prior Authorization of Antifungals, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Antifungal, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Antifungals, Topical at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antifungal, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antifungal, Topical, has a history of therapeutic failure, contraindication, or intolerance of the preferred Antifungals, Topical approved or medically accepted for the beneficiary’s diagnosis or indication.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antifungal, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Antifungals, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Antifungals, Oral that meet any of the following conditions must be prior authorized:

1. A non-preferred Antifungal, Oral. See the Preferred Drug List (PDL) for the list of preferred Antifungals, Oral at: https://papdl.com/preferred-drug-list.

2. An Antifungal, Oral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Antifungal, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antifungal, Oral, one of the following:
   a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Antifungals, Oral approved or medically accepted for the beneficiary’s diagnosis
   b. Has culture and sensitivity test results documenting that only a non-preferred Antifungal, Oral will be effective;

   AND

2. If a prescription for an Antifungal, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antifungal, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antihemophilia Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Antihemophilia Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihemophilia Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antihemophilia Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed the Antihemophilia Agent by a hematologist or hemophilia treatment center practitioner; AND

4. Does not have a contraindication to the requested medication; AND

5. For a non-preferred extended half-life factor VIII replacement agent, one of the following:
   a. Has documentation of failure to achieve clinical goals with the preferred extended half-life factor VIII replacement agent(s) approved or medically accepted for the beneficiary’s diagnosis or indication,
   b. Has a documented history of a contraindication or an intolerance to the preferred extended half-life factor VIII replacement agent(s) approved or medically accepted for the beneficiary’s diagnosis or indication,
   c. Both of the following:
      i. Has a current history (within the past 90 days) of being prescribed the same non-preferred extended half-life factor VIII replacement agent
      ii. Has documentation from the prescriber of a medical reason why the beneficiary should continue to use the non-preferred extended half-life factor VIII replacement agent (e.g., has a history of inhibitors and has not developed inhibitors while using the requested non-preferred agent)

See the Preferred Drug List (PDL) for the list of preferred Antihemophilia Agents at: https://papdl.com/preferred-drug-list;

AND

6. For a non-preferred extended half-life factor IX replacement agent, one of the following:
a. Has documentation of failure to achieve clinical goals with the preferred extended half-
life factor IX replacement agent(s) approved or medically accepted for the beneficiary’s
diagnosis or indication,

b. Has a documented history of a contraindication or an intolerance to the preferred
extended half-life factor IX replacement agent(s) approved or medically accepted for the
beneficiary’s diagnosis or indication,

c. Both of the following:

   i. Has a current history (within the past 90 days) of being prescribed the same non-
preferred extended half-life factor IX replacement agent

   ii. Has documentation from the prescriber of a medical reason why the beneficiary
should continue to use the non-preferred extended half-life factor IX replacement
agent (e.g., has a history of inhibitors and has not developed inhibitors while using
the requested non-preferred agent)

See the PDL for the list of preferred Antihemophilia Agents at: https://papdl.com/preferred-
drug-list;

**AND**

7. For a bypassing agent (e.g., FEIBA, NovoSeven RT, Sevenfact), one of the following:

a. Has a diagnosis of hemophilia A with inhibitors and at least one of the following:

   i. Both of the following:

      a) Is using the requested medication for routine prophylaxis

      b) One of the following:

         (i) Has documentation of failure to achieve clinical goals with Hemlibra
            (emicizumab),

         (ii) Has documentation from the prescriber of a medical reason why Hemlibra
            (emicizumab) cannot be used,

         (iii) Has a current history (within the past 90 days) of being prescribed the same
            bypassing agent for routine prophylaxis

   ii. Is using the requested medication for episodic/on-demand treatment or
       intermittent/periodic prophylaxis

b. Has a diagnosis of one of the following:

   i. Hemophilia B with inhibitors,
   ii. Acquired hemophilia,
   iii. Congenital factor VII deficiency,
   iv. Glanzmann’s thrombasthenia;
AND

8. For all other non-preferred Antihemophilia Agents, one of the following:
   a. Has documentation of failure to achieve clinical goals with the preferred Antihemophilia
      Agent(s) approved or medically accepted for the beneficiary’s diagnosis or indication,
   b. Has a documented history of a contraindication or an intolerance to the preferred
      Antihemophilia Agent(s) approved or medically accepted for the beneficiary’s diagnosis
      or indication,
   c. Has a diagnosis for which no preferred Antihemophilia Agents are appropriate,
   d. Both of the following:
      i. Has a current history (within the past 90 days) of being prescribed the same non-
         preferred Antihemophilia Agent
      ii. Has documentation from the prescriber of a clinical reason why the beneficiary
          should continue to use the non-preferred agent (e.g., has a history of inhibitors and
          has not developed inhibitors while using the requested non-preferred agent)

See the PDL for the list of preferred Antihemophilia Agents at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list);

AND

9. For Hemlibra (emicizumab), one of the following:
   a. Has a diagnosis of hemophilia A with inhibitors,
   b. Has a diagnosis of severe hemophilia A,
   c. Has a diagnosis of hemophilia A and a history of at least 1 spontaneous episode of
      bleeding into a joint or other serious bleeding event.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the
professional judgment of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be
approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ANTIHEMOPHILIA AGENTS: The
determination of medical necessity of a request for renewal of a prior authorization for an
Antihemophilia Agent that was previously approved will take into account whether the
beneficiary:

1. Has documentation of a positive clinical response to the requested Antihemophilia Agent;
   AND

2. Is being prescribed the Antihemophilia Agent for an indication that is included in FDA-
   approved package labeling OR a medically accepted indication; AND
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed the Antihemophilia Agent by a hematologist or hemophilia treatment center practitioner; AND

5. Does not have a contraindication to the requested medication.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihemophilia Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References


Requirements for Prior Authorization of Antihistamines, Minimally Sedating

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihistamines, Minimally Sedating that meet the following conditions must be prior authorized:

1. A non-preferred Antihistamine, Minimally Sedating. See the Preferred Drug List (PDL) for the list of preferred Antihistamines, Minimally Sedating at: https://papdl.com/preferred-drug-list.

2. An Antihistamine, Minimally Sedating with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. An Antihistamine, Minimally Sedating when there is a record of a recent paid claim for another Antihistamine, Minimally Sedating in the Department of Human Services' (Department) Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihistamine, Minimally Sedating, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antihistamine, Minimally Sedating, has a history of therapeutic failure, contraindication, or intolerance of the preferred Antihistamines, Minimally Sedating; AND

2. For therapeutic duplication, one of the following:
   a. Is being titrated to or tapered from another Antihistamine, Minimally Sedating
   b. Has a clinical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   AND

3. If a prescription for an Antihistamine, Minimally Sedating is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.
C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihistamine, Minimally Sedating. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Automated Prior Authorization**

Prior authorization of a prescription for an Antihistamine, Minimally Sedating with a prescribed quantity that does not exceed the quantity limit established by the Department will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 365 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.
I. Requirements for Prior Authorization of Antihypertensives, Sympatholytic

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihypertensives, Sympatholytic that meet any of the following conditions must be prior authorized:

1. A non-preferred Antihypertensive, Sympatholytic. See the Preferred Drug List (PDL) for the list of preferred Antihypertensives, Sympatholytic at: https://papdl.com/preferred-drug-list.

2. An Antihypertensive, Sympatholytic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to the quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihypertensive, Sympatholytic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antihypertensives, Sympatholytic AND

2. If a prescription for an Antihypertensive, Sympatholytic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihypertensive, Sympatholytic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antihyperuricemics

A. Prescriptions That Require Prior Authorization

Prescriptions for Antihyperuricemics that meet any of the following conditions must be prior authorized:

1. A non-preferred Antihyperuricemic. See the Preferred Drug List (PDL) for the list of preferred Antihyperuricemics at: https://papdl.com/preferred-drug-list.

2. An Antihyperuricemic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antihyperuricemic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. For a non-preferred Antihyperuricemic, one of the following:
   a. For a non-preferred xanthine oxidase inhibitor, has a documented history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of the preferred xanthine oxidase inhibitors,
   b. For a non-preferred single-ingredient colchicine agent, has a documented history of therapeutic failure of or a contraindication or an intolerance to the preferred single-ingredient colchicine agents that would not be expected to occur with the requested medication,
   c. For all other non-preferred Antihyperuricemics, has a documented history of therapeutic failure of or a contraindication or intolerance to maximum tolerated doses of the preferred Antihyperuricemics that are FDA-approved or medically accepted for the beneficiary’s diagnosis;
   **AND**

6. For Krystexxa (pegloticase), all of the following:
a. Is prescribed Krystexxa (pegloticase) by or in consultation with an appropriate specialist (i.e., rheumatologist, endocrinologist),

b. **Both** of the following:

i. Has a recent uric acid level that is above goal based on American College of Rheumatology guidelines

ii. **One** of the following:
   a) Continues to have frequent gout flares (≥2 flares/year)
   b) Has non-resolving subcutaneous tophi,

c. Will not be using Krystexxa (pegloticase) concomitantly with oral urate-lowering agents,

d. Has documentation of counseling regarding **both** of the following:

   i. Appropriate dietary and lifestyle modifications
   ii. Discontinuation of other medications known to precipitate gout attacks (e.g., thiazide diuretics);

**AND**

9. If a prescription for an Antihyperuricemic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**FOR RENEWALS OF PRIOR AUTHORIZATION FOR KRYSTEXXA (PEGLOTICASE):** The determination of medical necessity of a request for renewal of a prior authorization for Krystexxa (pegloticase) that was previously approved will take into account whether the beneficiary:

1. Has documentation of improvement in disease severity since initiating treatment with Krystexxa (pegloticase); **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed Krystexxa (pegloticase) by or in consultation with an appropriate specialist (i.e., rheumatologist, endocrinologist); **AND**

4. Does not have a history of a contraindication to Krystexxa (pegloticase); **AND**

5. Will not be using Krystexxa (pegloticase) concomitantly with oral urate-lowering agents;
6. If a prescription for Krystexxa (pegloticase) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antihyperuricemic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

C. References

Requirements for Prior Authorization of Antimalarials

A. Prescriptions That Require Prior Authorization

Prescriptions for Antimalarials that meet any of the following conditions must be prior authorized:

1. A non-preferred Antimalarial. See the Preferred Drug List (PDL) for the list of preferred Antimalarials at: https://papdl.com/preferred-drug-list.

2. An Antimalarial with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antimalarial, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antimalarial, **all** of the following:
   a. Is prescribed the Antimalarial for an indication included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
   b. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   c. **One** of the following:
      i. For treatment of malaria, has a history of therapeutic failure, contraindication, or intolerance of the preferred Antimalarials for the beneficiary’s diagnosis
      ii. For prevention of malaria, has a contraindication or intolerance of the preferred Antimalarials for the beneficiary’s indication;

   **AND**

2. If a prescription for an Antimalarial is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   **NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antimalarial. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a
physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Dose and Duration of Therapy**
Authorizations for Antimalarials consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

E. **References**

I. Requirements for Prior Authorization of Migraine Acute Treatment Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Migraine Acute Treatment Agents that meet any of the following conditions must be prior authorized:

1. A prescription for a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant).
2. A prescription for a serotonin (5-HT) 1F receptor agonist (ditan).
3. A prescription for an ergot alkaloid.
4. A non-preferred Migraine Acute Treatment Agent. See the Preferred Drug List (PDL) for the list of preferred Migraine Acute Treatment Agents at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list).
5. A Migraine Acute Treatment Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).
6. A Migraine Acute Treatment Agent when there is a record of a recent paid claim for another Migraine Acute Treatment Agent in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Migraine Acute Treatment Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a gepant for the preventive treatment of migraine, see the Migraine Prevention Agents policy; OR
2. Both of the following:
   a. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication
   b. Has a diagnosis confirmed according to the current International Headache Society Classification of Headache Disorders;

   **AND**

3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally

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recognized compendia, or peer-reviewed medical literature; AND

5. Does not have a contraindication to the prescribed medication; AND

6. For a gepant for the acute treatment of migraine, both of the following:
   a. One of the following:
      i. Has a history of therapeutic failure of at least two (5-HT \textsubscript{1B/1D}) receptor agonists (triptans)
      ii. Has a contraindication or intolerance to the preferred triptans
   b. If currently using a different gepant, one of the following:
      i. Will discontinue use of that gepant prior to starting the requested gepant
      ii. Has a medical reason for concomitant use of both gepants that is supported by peer-reviewed literature or national treatment guidelines;

   AND

7. For a ditan, has a history of trial and failure, contraindication, or intolerance to the preferred triptans; AND

8. For ergot alkaloids, has a history of trial and failure, contraindication, or intolerance to standard first-line abortive medications based on headache classification as recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society); AND

9. For a non-preferred Migraine Acute Treatment Agent, one of the following:
   a. For a non-preferred triptan, has a history of therapeutic failure, contraindication, or intolerance to the preferred triptans
   b. For all other non-preferred Migraine Acute Treatment Agents (e.g., gepants, ditans, ergot alkaloids, etc.), has a history of therapeutic failure, contraindication, or intolerance to the preferred Migraine Acute Treatment Agents approved or medically accepted for the beneficiary’s diagnosis or indication;

   AND

10. For therapeutic duplication, one of the following:
    a. Is being titrated to or tapered from another drug in the same class
    b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

    AND

11. If a prescription for a Migraine Acute Treatment Agent is for a quantity that exceeds the
quantity limit, the determination of whether the prescription is medically necessary will also take into account all of the following:

a. The guidelines set forth in the Quantity Limits Chapter,

b. Whether the beneficiary is prescribed the requested medication by one of the following:
   
   i. A neurologist
   
   ii. A headache specialist who is certified in headache medicine by the UCNS,

c. For the acute treatment of migraine, both of the following:

   i. One of the following:

   a) The beneficiary is using the requested medication in addition to at least one medication for migraine prevention (e.g., beta-blocker, anticonvulsant, antidepressant, CGRP monoclonal antibody)
   
   b) The beneficiary has a history of therapeutic failure, contraindication, or intolerance to all preventive migraine medications recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society)

   ii. Has documentation of an evaluation for the overuse of abortive medications, including opioids.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A MIGRAINE ACUTE TREATMENT AGENT: The determination of medical necessity of a request for renewal of a prior authorization for a Migraine Acute Treatment Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

2. Does not have a contraindication to the prescribed medication; AND

3. Has documentation of improvement in headache pain, symptoms, or duration; AND

4. If a prescription for a Migraine Acute Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account all of the following:

   a. The guidelines set forth in the Quantity Limits Chapter,
b. Whether the beneficiary is prescribed the requested medication by one of the following:

   i. A neurologist
   ii. A headache specialist who is certified in headache medicine by the UCNS,

c. For the acute treatment of migraine, both of the following:

   i. One of the following:

      a) The beneficiary is using the requested medication in addition to at least one medication for migraine prevention (e.g., beta-blocker, anticonvulsant, antidepressant, CGRP monoclonal antibody)
      b) The beneficiary has a history of therapeutic failure, contraindication, or intolerance to all preventive migraine medications recommended by current consensus guidelines (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society)

   ii. Has documentation of an evaluation for the overuse of abortive medications, including opioids.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Migraine Acute Treatment Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

C. References


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I. Requirements for Prior Authorization of Migraine Prevention Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Migraine Prevention Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Migraine Prevention Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a small molecule calcitonin gene-related peptide (CGRP) receptor antagonist (gepant) for the acute treatment of migraine, see the Migraine Acute Treatment Agents policy; OR

2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

5. Does not have a contraindication to the prescribed medication; AND

6. For a Migraine Prevention Agent prescribed for the prevention of migraine, all of the following:
   a. Is prescribed the Migraine Prevention Agent by or in consultation with one of the following:
      i. A neurologist
      ii. A headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties (UCNS),
   b. Has documentation of baseline average number of migraine days and headache days per month,
   c. Has averaged four or more migraine days per month over the previous three months,
   d. Has a diagnosis of migraine with or without aura confirmed according to the current International Headache Society Classification of Headache Disorders,
   e. One of the following:
      i. Has a history of therapeutic failure of at least one preventive medication from two of the following three classes:
a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
b) Antidepressants (e.g., amitriptyline, venlafaxine),
c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex)

ii. Has a contraindication or intolerance that prohibits a trial of at least one preventive medication from two of the following three classes:

a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
b) Antidepressants (e.g., amitriptyline, venlafaxine),
c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex);

AND

7. For a Migraine Prevention Agent prescribed for a diagnosis of episodic cluster headache, all of the following:

a. Is prescribed the Migraine Prevention Agent by or in consultation with one of the following:
   i. A neurologist
   ii. A headache specialist who is certified in headache medicine by the UCNS,

b. Has a diagnosis of episodic cluster headache confirmed according to the current International Headache Society Classification of Headache Disorders,

c. Has a documented history of therapeutic failure, contraindication, or intolerance of at least one other preventive medication recommended by current consensus guidelines for episodic cluster headache (such as guidelines from the American Academy of Neurology, American Academy of Family Physicians, American Headache Society);

AND

8. If currently using a Migraine Prevention Agent for the preventive treatment of migraine or the treatment of episodic cluster headaches, one of the following:

a. Will discontinue use of that Migraine Prevention Agent prior to starting the requested Migraine Prevention Agent
b. Has a medical reason for concomitant use of both Migraine Prevention Agents that is supported by peer-reviewed literature or national treatment guidelines;

AND

9. For a gepant, if currently using a different gepant, one of the following:

a. Will discontinue use of that gepant prior to starting the requested gepant
b. Has a medical reason for concomitant use of both gepants that is supported by peer-reviewed literature or national treatment guidelines;

AND
10. For Nurtec ODT for the prevention of migraine, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred CGRP monoclonal antibodies (mAbs) approved or medically accepted for the beneficiary’s indication; AND

11. For a non-preferred Migraine Prevention Agent, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the beneficiary’s diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Migraine Prevention Agents at: https://papdl.com/preferred-drug-list; AND

12. If a prescription for a Migraine Prevention Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A MIGRAINE PREVENTION AGENT:
The determination of medical necessity of a request for renewal of a prior authorization for a Migraine Prevention Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

2. Does not have a contraindication to the prescribed medication; AND

3. Is prescribed the Migraine Prevention Agent by or in consultation with one of the following:

   a. A neurologist
   b. A headache specialist who is certified in headache medicine by the UCNS;

   AND

4. For a Migraine Prevention Agent prescribed for the prevention of migraine, one of the following:

   a. Has a reduction in the average number of migraine days or headache days per month from baseline
   b. Experienced a decrease in severity or duration of migraines from baseline;

   AND
5. For a Migraine Prevention Agent prescribed for a diagnosis of episodic cluster headache, has documentation of a positive clinical response to the requested medication as evidenced by a reduction in cluster headache frequency from baseline; AND

6. For Nurtec ODT for the prevention of migraine, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred CGRP mAbs approved or medically accepted for the beneficiary’s indication; AND

7. For a non-preferred Migraine Prevention Agent, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred Migraine Prevention Agents approved or medically accepted for the beneficiary’s diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Migraine Prevention Agents at: https://papdl.com/preferred-drug-list; AND

8. If a prescription for a Migraine Prevention Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Migraine Prevention Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Migraine Prevention Agents will be approved as follows:

1. Initial requests for prior authorization of Migraine Prevention Agents prescribed for the prevention of migraine will be approved for up to 6 months.

2. Renewals of requests for prior authorization of Migraine Prevention Agents prescribed for the prevention of migraine will be approved for up to 12 months.

3. Initial requests for prior authorization of Migraine Prevention Agents prescribed for a diagnosis of episodic cluster headache will be approved for up to 4 months.

4. Renewals of requests for prior authorization of Migraine Prevention Agents prescribed for a diagnosis of episodic cluster headache will be approved for up to 6 months.
E. References


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I. Requirements for Prior Authorization of Antiparasitics, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Antiparasitic, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Antiparasitics, Topical at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiparasitic, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For lindane, all of the following:
   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiparasitics, Topical approved or medically accepted for the beneficiary’s diagnosis,
   b. Weighs ≥50 kilograms,
   c. Does not take medication that may reduce the seizure threshold (such as but not limited to meperidine, cyclosporine, theophylline)

   AND

2. For all other non-preferred Antiparasitic, Topicals, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiparasitics, Topical approved or medically accepted for the beneficiary’s diagnosis.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for an Antiparasitic, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

D. Dose and Duration of Therapy

Requests for prior authorization of Antiparasitics, Topical will be approved for a dose and duration of therapy consistent with FDA-approved package labeling.
I. Requirements for Prior Authorization of Antipsoriatics, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for Antipsoriatics, Topical that meet the following conditions must be prior authorized:

1. A non-preferred Antipsoriatic, Topical. See Preferred Drug List (PDL) for the list of preferred Antipsoriatics, Topical at: https://papdl.com/preferred-drug-list.

2. A topical aryl hydrocarbon (AhR) receptor agonist.

3. A topical phosphodiesterase type 4 (PDE4) inhibitor.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antipsoriatic, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antipsoriatic, Topical for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, national compendia, or peer-reviewed medical literature; AND

3. Does not have a contraindication to the prescribed medication; AND

4. For a topical AhR agonist, both of the following:
   a. Has a history of therapeutic failure of or a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary’s diagnosis
   b. Has a history of therapeutic failure of or a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary’s diagnosis; AND

5. For a topical PDE4 inhibitor, both of the following:
   a. Has a history of therapeutic failure of or a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary’s diagnosis
   b. Has a history of therapeutic failure of or a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary’s diagnosis;
AND

6. For all other non-preferred Antipsoriatrics, Topical, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antipsoriatrics, Topical approved or medically accepted for the treatment of the beneficiary’s diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antipsoriatric, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antipsychotics

A. Prescriptions That Require Prior Authorization

Prescriptions for Antipsychotics that meet any of the following conditions must be prior authorized:

1. A non-preferred Antipsychotic. See the Preferred Drug List (PDL) for the list of preferred Antipsychotics at: https://papdl.com/preferred-drug-list.

2. An Antipsychotic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. An Antipsychotic when prescribed for a child under 18 years of age.

4. An atypical Antipsychotic when there is a record of a recent paid claim for another atypical Antipsychotic in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

5. A typical Antipsychotic when there is a record of a recent paid claim for another typical Antipsychotic in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antipsychotic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antipsychotic, **one** of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance (such as, but not limited to, diabetes, obesity, etc.) to the preferred Antipsychotics
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antipsychotic (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

   **AND**

2. For an Antipsychotic for a child under the age of 18 years, **all** of the following:

   a. Has severe behavioral problems related to psychotic or neuro-developmental disorders such as seen in, but not limited to, the following diagnoses:

      i. Autism spectrum disorder,
ii. Intellectual disability,
iii. Conduct disorder,
iv. Bipolar disorder,
v. Mood disorders with psychotic features,
vi. Tic disorder, including Tourette’s syndrome,
vii. Transient encephalopathy,
viii. Schizophrenia and schizophrenia-related disorders,

b. One of the following:

i. If less than 14 years of age, is being prescribed the medication by or in consultation with one of the following:
   a) Pediatric neurologist,
   b) Child and adolescent psychiatrist,
   c) Child development pediatrician

ii. If 14 years of age or older, is being prescribed the medication by or in consultation with one of the following:
   a) Pediatric neurologist,
   b) Child and adolescent psychiatrist,
   c) Child development pediatrician,
   d) General psychiatrist,

c. Has chart documented evidence of a comprehensive evaluation,

d. Has a documented plan of care that includes non-pharmacologic therapies (e.g., evidence-based behavioral, cognitive, and family based therapies) when indicated according to national treatment guidelines,

e. Has documented baseline monitoring of weight or body mass index (BMI), blood pressure, fasting glucose or hemoglobin A1c, fasting lipid panel, and extrapyramidal symptoms (EPS) using the Abnormal Involuntary Movement Scale (AIMS);

AND

3. For therapeutic duplication, one of the following:

a. For an atypical Antipsychotic, is being titrated to or tapered from another atypical Antipsychotic,

b. For a typical Antipsychotic, is being titrated to or tapered from another typical Antipsychotic,

c. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND
4. If a prescription for an Antipsychotic is in a quantity that exceeds the quantity limit, the
determination of whether the prescription is medically necessary will also take into account
the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the
professional judgment of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be
approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR PREFERRED and NON-PREFERRED
ANTIPSYCHOTICS FOR CHILDREN UNDER 18 YEARS OF AGE: The determination of
medical necessity of a request for renewal of a prior authorization for an Antipsychotic for a
child under 18 years of age that was previously approved will take into account whether the
beneficiary:

1. Has all of the following:
   a. Documented improvement in target symptoms,
   b. Documented monitoring of weight or BMI quarterly,
   c. Documented monitoring of blood pressure, fasting glucose or hemoglobin A1c, fasting
      lipid panel, and EPS using AIMS after the first 3 months of therapy and then annually,
   d. Documented plan for taper/discontinuation of the Antipsychotic or rationale for
      continued use.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the
professional judgment of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be
approved.

C. Clinical Review Process

Except as noted below, prior authorization personnel will review the request for prior
authorization and apply the clinical guidelines in Section B. above to assess the medical
necessity of a prescription for an Antipsychotic. If the guidelines in Section B. are met, the
reviewer will prior authorize the prescription. If the guidelines are not met, the prior
authorization request will be referred to a physician reviewer (a psychiatrist) for a medical
necessity determination. Such a request for prior authorization will be approved when, in the
professional judgment of the physician reviewer (a psychiatrist), the services are medically
necessary to meet the medical needs of the beneficiary.

All requests for prior authorization of an antipsychotic medication for a child under 18 years of
age will be automatically forwarded to a physician reviewer (a psychiatrist) for a medical
necessity determination. The physician reviewer (a psychiatrist) will prior authorize the
prescription based on one of the following:

1. The guidelines in Section B. 2. are met.
2. In the professional judgment of the physician reviewer (a psychiatrist), the services are
   medically necessary to meet the medical needs of the beneficiary.
D. **Dose and Duration of Therapy**

Approvals of requests for prior authorization of prescriptions for an Antipsychotic for a child under 18 years of age will be approved as follows:

1. Up to 3 months for an initial request.
2. Up to 12 months for a renewal of a previously approved request.

E. **References**

2. Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes, Diabetes Care, 27:2, February 2004.
I. Requirements for Prior Authorization of Antivirals, CMV

A. Prescriptions That Require Prior Authorization

Prescriptions for Antivirals, CMV that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiviral, CMV. See the Preferred Drug List (PDL) for the list of preferred Antivirals, CMV at: https://papdl.com/preferred-drug-list.

2. A prescription for letermovir.

3. An Antiviral, CMV with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiviral, CMV, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Antiviral, CMV for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Does not have a contraindication to the requested medication; AND

5. For letermovir, all of the following:
   a. Is prescribed letermovir by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, infectious disease specialist, or transplant specialist),
   b. Has received a hematopoietic stem cell transplant,
   c. One of the following:
      i. Is CMV-seropositive
      ii. Is at high risk for CMV reactivation,
   d. For primary prophylaxis of CMV infection/disease after allogeneic hematopoietic
stem cell transplant, will initiate or has initiated treatment with letermovir between
day 0 and day 28 post-transplant;

AND

6. For maribavir, all of the following:
   a. Is prescribed maribavir by or in consultation with an appropriate specialist (i.e.,
      hematologist/oncologist, infectious disease specialist, or transplant specialist),
   b. If currently taking ganciclovir or valganciclovir, will discontinue ganciclovir or
      valganciclovir prior to starting maribavir,
   c. For treatment of post-transplant CMV infection/disease, one of the following:
      i. Is prescribed maribavir for continuation of treatment upon inpatient discharge,
      ii. Has a history of therapeutic failure of or a contraindication or an intolerance to at
          least one of the following:
          a) Ganciclovir,
          b) Valganciclovir,
          c) Cidofovir,
          d) Foscarnet,
      iii. Has culture and sensitivity results documenting that only maribavir will be
effective;

AND

7. For all other non-preferred Antivirals, CMV, one of the following:
   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the
      preferred Antivirals, CMV approved or medically accepted for the beneficiary’s
      diagnosis or indication
   b. Has culture and sensitivity results showing both of the following:
      i. The beneficiary’s infection is not susceptible to the preferred Antivirals, CMV
      ii. The beneficiary’s infection is susceptible to the requested non-preferred Antiviral,
         CMV;

AND

8. If a prescription for an Antiviral, CMV is for a quantity that exceeds the quantity limit, the
determination of whether the prescription is medically necessary will also take into
account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the
professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antiviral, CMV. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Antiparkinson’s Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Antiparkinson’s Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiparkinson’s Agent. See the Preferred Drug List (PDL) for the list of preferred Antiparkinson’s Agents at: https://papdl.com/preferred-drug-list.

2. An Antiparkinson’s Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiparkinson’s Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antiparkinson’s Agent, one of the following:

   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antiparkinson’s Agents
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Antiparkinson’s Agent

   **AND**

2. If a prescription for an Antiparkinson’s Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   **NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

B. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antiparkinson’s Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antipsoriatics, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Antipsoriatics, Oral that meets any of the following conditions must be prior authorized:

1. A non-preferred Antipsoriatic, Oral. See the Preferred Drug List (PDL) for the list of preferred Antipsoriatics, Oral at: https://papdl.com/preferred-drug-list.

2. An Antipsoriatic, Oral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antipsoriatic, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antipsoriatic, Oral, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Antipsoriatics, Oral AND

2. If a prescription for an Antipsoriatic, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antipsoriatic, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Antivirals, Herpes

A. Prescriptions That Require Prior Authorization

Prescriptions for Antivirals, Herpes that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiviral, Herpes. See the Preferred Drug List (PDL) for the list of preferred Antivirals, Herpes at: https://papdl.com/preferred-drug-list.

2. An Antiviral, Herpes with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiviral, Herpes, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antiviral, Herpes, has a history of therapeutic failure, intolerance, or contraindication of the preferred Antivirals, Herpes approved for the beneficiary’s diagnosis or indication; AND

2. If a prescription for an Antiviral, Herpes is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Antiviral, Herpes. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Antivirals, Influenza

A. Prescriptions That Require Prior Authorization

Prescriptions for Antivirals, Influenza that meet any of the following conditions must be prior authorized:

1. A non-preferred Antiviral, Influenza. See the Preferred Drug List (PDL) for the list of preferred Antivirals, Influenza at: https://papdl.com/preferred-drug-list.

2. An Antiviral, Influenza with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Antiviral, Influenza, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Antiviral, Influenza, has a history of intolerance or contraindication of the preferred Antivirals, Influenza; AND

2. If a prescription for an Antiviral, Influenza is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for an Antiviral, Influenza. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Anxiolytics

A. Prescriptions That Require Prior Authorization

Prescriptions for Anxiolytics that meet any of the following conditions must be prior authorized:

1. A non-preferred Anxiolytic. See the Preferred Drug List (PDL) for the list of preferred Anxiolytics at: https://papdl.com/preferred-drug-list.

2. An Anxiolytic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. An Anxiolytic benzodiazepine when prescribed for a beneficiary under 21 years of age.

4. An Anxiolytic benzodiazepine when a beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

5. An Anxiolytic benzodiazepine when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

6. A prescription for an Anxiolytic benzodiazepine when there is a record of 2 or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System within the past 30 days.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Anxiolytic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For an Anxiolytic benzodiazepine for a beneficiary under 21 years of age, one of the following:

   a. Has a diagnosis of one of the following:
      i. Seizure disorder,
      ii. Chemotherapy induced nausea and vomiting,
      iii. Cerebral palsy,
      iv. Spastic disorder,
      v. Dystonia,
      vi. Catatonia

   b. Is receiving palliative care;

   AND
2. For an Anxiolytic benzodiazepine for a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, both of the following:

   a. Is prescribed the buprenorphine agent and the benzodiazepine by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
   b. Has an acute need for therapy with the benzodiazepine;

   **AND**

3. For therapeutic duplication, one of the following:

   a. Is being titrated to or tapered from a drug in the same class
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   **AND**

4. When there is a record of 2 or more paid claims for a benzodiazepine, both of the following:

   a. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed literature or national treatment guidelines
   b. The multiple prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s);

   **AND**

5. For a non-preferred Anxiolytic, has a history of therapeutic failure, contraindication, or intolerance of the preferred Anxiolytics; **AND**

6. For an Anxiolytic that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance), one of the following:

   a. Meets the guidelines in B.1.
   b. Has documentation that the prescriber or the prescriber's delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary's controlled substance prescription history;

   **AND**

7. If a prescription for an Anxiolytic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   **NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to

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meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Anxiolytic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Beta Blockers

A. Prescriptions That Require Prior Authorization

Prescriptions for Beta Blockers that meet any of the following conditions must be prior authorized:

1. A non-preferred Beta Blocker. See the Preferred Drug List (PDL) for the list of preferred Beta Blockers at: https://papdl.com/preferred-drug-list.

2. A Beta Blocker with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacieservices/quantitylimitslist/index.htm.

3. A Beta Blocker when there is a record of a recent paid claim for another Beta Blocker in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. A prescription for Hemangeol (propranolol hydrochloride oral solution).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Beta Blocker, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Hemangeol (propranolol hydrochloride oral solution), all of the following:
   a. Is prescribed Hemangeol (propranolol hydrochloride oral solution) for an indication that is included in the U.S. Food and Drug Administration (FDA)approved package labeling,
   b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   c. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   d. Is prescribed Hemangeol (propranolol hydrochloride oral solution) by or in consultation with an appropriate specialist (e.g., pediatric dermatologist, hematologist, or oncologist);

   AND

2. For a non-preferred Beta Blocker, has a history of therapeutic failure, contraindication, or intolerance of the preferred Beta Blockers approved or medically accepted for the beneficiary’s diagnosis; AND
3. For therapeutic duplication, one of the following:
   a. Is being titrated to or tapered from a drug in the same class
   b. Has a clinical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   AND

4. If a prescription for a Beta Blocker is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR HEMANGEOL (PROPRANOLOL HYDROCHLORIDE ORAL SOLUTION): The determination of medical necessity of a request for renewal of a prior authorization for Hemangeol (propranolol hydrochloride oral solution) that was previously approved will take into account whether the beneficiary:

1. Has documentation of improvement in disease severity since initiating treatment with Hemangeol (propranolol hydrochloride oral solution); AND

2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed Hemangeol (propranolol hydrochloride oral solution) by or in consultation with an appropriate specialist (e.g., pediatric dermatologist, hematologist, or oncologist).

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Beta Blocker. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a
physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. **Requirements for Prior Authorization of Bile Salts**

A. **Prescriptions That Require Prior Authorization**

   Prescriptions for Bile Salts that meet any of the following conditions must be prior authorized:

   1. A non-preferred Bile Salt. See the Preferred Drug List (PDL) for the list of preferred Bile Salts at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list).

   2. A Bile Salt with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

   3. A prescription for cholic acid.

   4. A prescription for obeticholic acid.

B. **Review of Documentation for Medical Necessity**

   In evaluating a request for prior authorization of a prescription for a Bile Salt, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

   1. Is prescribed the Bile Salt for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

   2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

   3. Does not have a contraindication to the requested medication; **AND**

   4. For cholic acid, **both** of the following:

      a. Is prescribed cholic acid by or in consultation with a hepatologist or pediatric gastroenterologist

      b. Has documentation of a medical history and lab test results that support the beneficiary’s diagnosis;

      **AND**

   5. For obeticholic acid, **all** of the following:

      a. Is prescribed obeticholic acid by or in consultation with a hepatologist or gastroenterologist,

      b. Has documentation of a medical history and lab test results that support the beneficiary’s diagnosis,
c. Has a history of therapeutic failure of or a contraindication or an intolerance to optimally titrated doses of ursodeoxycholic acid (UDCA),

d. **One** of the following:

   i. Will be prescribed obeticholic acid in combination with UDCA
   ii. Has a contraindication or an intolerance to UDCA;

**AND**

6. For all other non-preferred Bile Salts, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Bile Salts approved or medically accepted for the beneficiary's diagnosis; **AND**

7. If a prescription for a Bile Salt is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**FOR RENEWALS OF PRIOR AUTHORIZATION FOR BILE SALTS:** The determination of medical necessity of a request for renewal of a prior authorization for a Bile Salt that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

2. Does not have a contraindication to the requested medication; **AND**

3. For cholic acid, **all** of the following:

   a. Is prescribed cholic acid by or in consultation with a hepatologist or pediatric gastroenterologist,
   b. Has documented improvement in liver function within the first 3 months of treatment,
   c. Does not have complete biliary obstruction, persistent clinical or laboratory indicators of worsening liver function, or cholestasis;

   **AND**

4. For obeticholic acid, **both** of the following:

   a. Is prescribed obeticholic acid by or in consultation with a hepatologist or gastroenterologist
   b. Has documentation of a positive response to obeticholic acid as evidenced by liver function tests;
5. For all other non-preferred Bile Salts, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Bile Salts approved or medically accepted for the beneficiary’s diagnosis; **AND**

6. If a prescription for a Bile Salt is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**C. Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Bile Salt. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

**D. References**

I. Requirements for Prior Authorization of Bladder Relaxant Preparations

A. Prescriptions That Require Prior Authorization

Prescriptions for Bladder Relaxant Preparations that meet any of the following conditions must be prior authorized:

1. A non-preferred Bladder Relaxant Preparation. See the Preferred Drug List (PDL) for the list of preferred Bladder Relaxant Preparations at: https://papdl.com/preferred-drug-list.

2. A Bladder Relaxant Preparation with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A urinary antispasmodic Bladder Relaxant Preparation when there is a record of a recent paid claim for another urinary antispasmodic Bladder Relaxant Preparation in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. A urinary beta-3 agonist Bladder Relaxant Preparation when there is a record of a recent paid claim for another urinary beta-3 agonist Bladder Relaxant Preparation in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Bladder Relaxant Preparation, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Bladder Relaxant Preparation, has a history of therapeutic failure, contraindication, or intolerance of the preferred Bladder Relaxant Preparations; AND

2. For therapeutic duplication, one of the following:
   a. For a urinary antispasmodic Bladder Relaxant Preparation, is being titrated to or tapered from another urinary antispasmodic Bladder Relaxant Preparation,
   b. For a urinary beta-3 agonist Bladder Relaxant Preparation, is being titrated to or tapered from another urinary beta-3 agonist Bladder Relaxant Preparation,
   c. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   AND

3. If a prescription for a Bladder Relaxant Preparation is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Bladder Relaxant Preparation. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Blood Glucose Meters and Test Strips

A. Prescriptions That Require Prior Authorization

Prescriptions for Blood Glucose Meters (glucometers) and Test Strips that meet any of the following conditions must be prior authorized:


2. A non-preferred Blood Glucose Test Strip. See the Preferred Drug List (PDL) for the list of preferred Blood Glucose Test Strips at: https://papdl.com/preferred-drug-list.

3. A Blood Glucose Meter or Test Strip with a prescribed quantity that exceeds the quantity limit. Quantity limits for test strips are 100 test strips per month except for members with gestational diabetes. These members will be restricted to 300 test strips a month.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Blood Glucose Meter or Test Strip, the determination of whether the requested product is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Blood Glucose Meter, has a documented history of trial and failure of the use of the preferred Blood Glucose Meters; AND

2. For a non-preferred Blood Glucose Test Strip, has a documented history of trial and failure of the use of the preferred Blood Glucose Meters; AND

3. If a prescription for a Blood Glucose Meter or Test Strip is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Blood Glucose Meter or Test Strip. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for
prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Bone Density Regulators

A. Prescriptions That Require Prior Authorization

Prescriptions for Bone Density Regulators that meet any of the following conditions must be prior authorized:

1. A non-preferred Bone Density Regulator. See the Preferred Drug List (PDL) for the list of preferred Bone Density Regulators at: https://papdl.com/preferred-drug-list.

2. A Bone Density Regulator with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Bone Density Regulator, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Bone Density Regulator, all of the following:
   a. Is prescribed the Bone Density Regulator for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
   b. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   c. Does not have a history of a contraindication to the prescribed medication,
   d. For an osteoporosis-related condition, was evaluated for secondary causes of osteoporosis including complete blood count (CBC), vitamin D, ionized calcium, phosphorus, albumin, total protein, creatinine, liver enzymes (specifically alkaline phosphatase), intact parathyroid hormone (PTH), thyroid stimulating hormone (TSH), urinary calcium excretion, and testosterone (if a male),
   e. For an anabolic agent, all of the following:
      i. One of the following:
         a) Has a T-score of -3.5 or below, a T-score of -2.5 or below and a history of fragility fracture, or multiple vertebral fractures
         b) Has a history of therapeutic failure,¹ intolerance, or contraindication to bisphosphonates,

¹ Therapeutic failure for an osteoporosis-related condition is defined as documented continued bone loss or fragility fracture after two (2) or more years despite treatment with a bisphosphonate.

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ii. Has not received a cumulative treatment duration that exceeds recommendations in the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,

iii. For Forteo (teriparatide) and Tymlos (abaloparatide), does not have a history of any of the following:
   a) Paget’s disease,
   b) Bone metastases,
   c) Skeletal malignancies,
   d) Metabolic bone disease other than osteoporosis,
   e) Hypercalcemic disorders,
   f) Unexplained elevations of alkaline phosphatase,
   g) Open epiphyses,
   h) Prior external beam or implant radiation therapy involving the skeleton,

iv. For Evenity (romosozumab), does not have a history of myocardial infarction or stroke,

v. For Evenity (romosozumab) or Tymlos (abaloparatide), has a documented history of intolerance or contraindication to teriparatide,

vi. For Forteo, has a contraindication or intolerance to teriparatide that would not be expected to occur with Forteo,

f. For Evista (raloxifene), all of the following:
   i. Does not have a documented history of venous thromboembolic events or breast cancer,
   
   ii. For women with a risk factor for stroke (such as prior stroke or transient ischemic attack (TIA), atrial fibrillation, hypertension, or cigarette smoking), the increased risk of death due to stroke has been discussed with the beneficiary and documented by the prescriber,

   iii. One of the following:
      a) Is a postmenopausal woman at high risk of fracture\(^1\) and high risk for invasive breast cancer as defined by one of the following:
      
         (i) Prior biopsy with lobular carcinoma in situ (LCIS) or atypical hyperplasia,
         (ii) One or more first degree relatives with breast cancer,
         (iii) A 5-year predicted risk of breast cancer $\geq 1.66\%$ (based on the modified Gail

\(^1\) Therapeutic failure for an osteoporosis-related condition is defined as documented continued bone loss or fragility fracture after two (2) or more years despite treatment with a bisphosphonate.

\(^2\) High risk is defined as one of the following: T-score between -1.0 and -2.5 and a history of fragility fracture of the proximal humerus, pelvis, or distal forearm; T-score between -1.0 and -2.5 at the femoral neck, total hip, or lumbar spine and a 10-year probability of a hip fracture $\geq 3\%$ or a 10-year probability of a major osteoporosis-related fracture $\geq 20\%$ based on the US-adapted World Health Organization (WHO) algorithm; T-score $-2.5$ or below at the femoral neck, total hip, or lumbar spine; OR history of low-trauma spine or hip fracture, regardless of bone density.
b) Is a postmenopausal woman at high risk of fracture with a history of therapeutic failure,¹ intolerance, or contraindication to oral bisphosphonates,

g. For Xgeva (denosumab), one of the following:

i. Has a history of therapeutic failure, intolerance, or contraindication to the preferred zoledronic acid

ii. Is being treated for giant cell tumor of the bone,

h. For all other non-preferred Bone Density Regulators, all of the following:

i. Is at high risk of fracture,²

ii. Has a documented history of therapeutic failure,¹ intolerance, or contraindication to the preferred Bone Density Regulators approved for the beneficiary’s diagnosis,

iii. For a parenteral bisphosphonate, has a documented history of contraindication or intolerance to oral bisphosphonates;

**AND**

2. If a prescription for a Bone Density Regulator is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR BONE DENSITY REGULATORS: The determination of medical necessity of a request for renewal of a prior authorization for Bone Density Regulator that was previously approved will take into account whether the beneficiary:

1. Based on the prescriber’s assessment, continues to benefit from the prescribed Bone Density Regulator; **AND**

2. If a prescription for a Bone Density Regulator is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a
Bone Density Regulator. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Dose and Duration of Therapy**

Requests for prior authorization of Bone Density Regulators will be approved as follows:

1. Initial and renewal requests for prior authorization of Bone Density Regulators will be approved for up to 12 months.

2. Prior authorization of Forteo (teriparatide) and Tymlos (abaloparatide) will be limited to 2 years cumulative duration of treatment.

3. Prior authorization of Evenity (romosozumab) will be limited to 12 months cumulative duration of treatment.

E. **References:**


5. Forteo (teriparatide) Prescribing Information. Indianapolis, IN; Lilly; October 2016.


8. Zometa (zoledronic acid) Prescribing Information. East Hanover, NJ; Novartis Pharmaceuticals Corporation; December 2018.

9. Evista (raloxifene) Prescribing Information. Indianapolis, IN; Lilly; June 2018.


I. **Requirements for Prior Authorization of Botulinum Toxins (Type A and Type B)**

A. **Prescriptions That Require Prior Authorization**

   All prescriptions for Botulinum Toxins must be prior authorized.

B. **Review of Documentation for Medical Necessity**

   In evaluating a request for prior authorization of a prescription for a Botulinum Toxin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

   1. Is prescribed the Botulinum Toxin for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding a cosmetic condition; **AND**

   2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

   3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

   4. Does not have a contraindication to the prescribed medication; **AND**

   5. Has documentation of the proposed injection site(s) and the dose that will be injected into each site; **AND**

   6. For a non-preferred Botulinum Toxin, has a history of therapeutic failure, contraindication, or intolerance of the preferred Botulinum Toxins approved or medically accepted for the beneficiary’s diagnosis or indication. See the Preferred Drug List (PDL) for the list of preferred Botulinum Toxins at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list); **AND**

   7. For a diagnosis of chronic spasticity, all of the following:

      a. Has documented spasticity that interferes with activities of daily living or is expected to result in joint contracture with future growth,

      b. If the beneficiary is age 18 or older, has documented therapeutic failure, contraindication, or intolerance to one oral medication for spasticity,

      c. If the beneficiary developed contractures, the beneficiary has been considered for surgical intervention,

      d. The Botulinum Toxin is being requested to enhance function or allow for additional therapeutic modalities to be employed,

      e. Will use the requested Botulinum Toxin in conjunction with other appropriate therapeutic modalities such as physical therapy, occupational therapy, gradual splinting, etc.;
AND

8. For a diagnosis of axillary hyperhidrosis, has a history of therapeutic failure, contraindication, or intolerance to a topical agent such as 20 percent aluminum chloride; **AND**

9. For a diagnosis of chronic migraine headache, **all** of the following:
   a. **One** of the following:
      i. Has a history of therapeutic failure of at least **one** migraine preventive medication from at least **two** of the following three classes:
         a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
         b) Antidepressants (e.g., amitriptyline, venlafaxine),
         c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex),
      ii. Has a history of contraindication or intolerance that prohibits a trial of at least **one** migraine preventive medication from at least **two** of the following three classes:
         a) Beta-blockers (e.g., metoprolol, propranolol, timolol),
         b) Antidepressants (e.g., amitriptyline, venlafaxine),
         c) Anticonvulsants (e.g., topiramate, valproic acid, divalproex),
   b. Has a diagnosis of chronic migraine headache according to the current International Headache Society Classification of Headache Disorders that is not attributed to other causes including medication overuse,
   c. Is prescribed the Botulinum Toxin by or in consultation with **one** of the following:
      i. A neurologist
      ii. A headache specialist who is certified in headache medicine by the United Council for Neurologic Subspecialties (UCNS); **AND**

10. For a diagnosis of urinary incontinence due to detrusor overactivity associated with a neurologic condition, has a history of therapeutic failure, contraindication, or intolerance to at least 1 anticholinergic medication used in the treatment of urinary incontinence; **AND**

11. For a diagnosis of overactive bladder with symptoms of urge urinary incontinence, urgency, and frequency, has a history of therapeutic failure, contraindication, or intolerance to at least 2 agents (e.g., antimuscarinics or beta-3 adrenergic agonists) used in the treatment of overactive bladder; **AND**

12. If a prescription for a Botulinum Toxin is in a quantity that exceeds the dosing limits, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to
quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR BOTULINUM TOXINS: The determination of medical necessity of a request for renewal of a prior authorization for a Botulinum Toxin that was previously approved will take into account whether the beneficiary:

1. If the frequency of injection exceeds the dose and duration of therapy limits, has documentation of both of the following:
   a. The previous treatment was well tolerated but inadequate
   b. Medical literature supports more frequent dosing intervals as safe and effective for the diagnosis and requested dose

   AND

2. If the frequency of injection is consistent with the dose and duration of therapy limits, has documentation of both of the following:
   a. Tolerability and a positive clinical response to the medication
   b. The symptoms returned to such a degree that repeat injection is required.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Botulinum Toxin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of Botulinum Toxins will be consistent with package labeling.
Requests for authorization of a Botulinum Toxin will not be approved for one year from the most recent injection when there is no benefit after two sequential therapies using maximum doses.

E. References:


Requirements for Prior Authorization of BPH (Benign Prostatic Hyperplasia) Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for BPH Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred BPH Treatment. See the Preferred Drug List (PDL) for the list of preferred BPH Treatments at: https://papdl.com/preferred-drug-list.

2. A BPH Treatment with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. An alpha blocker when there is a record of a recent paid claim for another alpha-blocker in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. A 5-alpha reductase inhibitor when there is a record of a recent paid claim for another 5alpha reductase inhibitor in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a BPH Treatment, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred BPH Treatment, has a history of therapeutic failure, contraindication, or intolerance to the preferred BPH Treatments; **AND**

2. For a phosphodiesterase 5 (PDE5) inhibitor (e.g., tadalafil), has a diagnosis of BPH; **AND**

3. For therapeutic duplication, **one** of the following:

   a. Is being titrated to or tapered from another BPH Treatment with the same mechanism of action
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   **AND**

4. If a prescription for a BPH Treatment is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.
C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a BPH Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Bronchodilators, Beta Agonists

A. Prescriptions That Require Prior Authorization

Prescriptions for Bronchodilators, Beta Agonists that meet any of the following conditions must be prior authorized:

1. A non-preferred Bronchodilator, Beta Agonist. See the Preferred Drug List (PDL) for the list of preferred Bronchodilators, Beta Agonists at: https://papdl.com/preferred-drug-list.

2. A Bronchodilator, Beta Agonist with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. An inhaled long-acting Bronchodilator, Beta Agonist when there is a record of a recent paid claim for another agent that contains an inhaled long-acting beta agonist in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Bronchodilator, Beta Agonist, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:
   
   a. For a non-preferred inhaled short-acting Bronchodilator, Beta Agonist, has a history of therapeutic failure, contraindication, or intolerance of the preferred inhaled short-acting Bronchodilators, Beta Agonists,
   
   b. For a non-preferred inhaled long-acting Bronchodilator, Beta Agonist, has a history of therapeutic failure, contraindication, or intolerance of the preferred inhaled long-acting Bronchodilators, Beta Agonists,
   
   c. For a non-preferred oral Bronchodilator, Beta Agonist, has a history of therapeutic failure, contraindication, or intolerance of the preferred inhaled Bronchodilators, Beta Agonists approved or medically accepted for the beneficiary’s diagnosis or indication;

   **AND**

   2. For therapeutic duplication, **one** of the following:

   a. For an inhaled long-acting beta agonist, is being titrated to or tapered from another inhaled long-acting beta agonist,
   
   b. Has a clinical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   **AND**
3. If a prescription for a Bronchodilator, Beta Agonist is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Bronchodilator, Beta Agonist. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Calcium Channel Blockers

A. Prescriptions That Require Prior Authorization

Prescriptions for Calcium Channel Blockers that meet any of the following conditions must be prior authorized:

1. A non-preferred Calcium Channel Blocker. See the Preferred Drug List (PDL) for the list of preferred Calcium Channel Blockers at: https://papdl.com/preferred-drug-list.

2. A Calcium Channel Blocker with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. A Calcium Channel Blocker when there is a record of a recent paid claim for another Calcium Channel Blocker in Point-of-Sale On-Line Claims Adjudication System.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Calcium Channel Blocker, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Calcium Channel Blocker, has a history of therapeutic failure, contraindication, or intolerance of the preferred Calcium Channel Blockers; **AND**

2. For therapeutic duplication, **one** of the following:
   a. Is being titrated to, or tapered from, a drug in the same class
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

**AND**

3. If a prescription for a Calcium Channel Blocker is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for a Calcium Channel Blocker. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity
determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Cephalosporins

A. Revisions to Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Cephalosporin must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Cephalosporins at: https://papdl.com/preferred-drug-list.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Cephalosporin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:
   
   a. Has a history of therapeutic failure, intolerance, or contraindication of the preferred Cephalosporins
   b. Has culture and sensitivity test results documenting that only non-preferred Cephalosporins will be effective.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Cephalosporin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Colony Stimulating Factors

A. Revisions to Prescriptions That Require Prior Authorization

All prescriptions for Colony Stimulating Factors must be prior authorized.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Colony Stimulating Factor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Colony Stimulating Factor for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed the Colony Stimulating Factor by or in consultation with a hematologist or oncologist; AND

4. Does not have a history of a contraindication to the prescribed Colony Stimulating Factor; AND

5. For primary prophylaxis of chemotherapy-induced febrile neutropenia in patients with non-myeloid malignancies, one of the following:
   a. Will be receiving a chemotherapy regimen with an expected incidence of febrile neutropenia > 20% as defined by the National Comprehensive Cancer Network (NCCN)
   b. Has risk factors for developing febrile neutropenia as defined by the NCCN; AND

6. For a prescription for Neulasta (pegfilgrastim), will not be receiving the medication during the period beginning 14 days before and ending 24 hours after administration of cytotoxic chemotherapy; AND

7. For a non-preferred Colony Stimulating Factor, has a history of therapeutic failure, contraindication, or intolerance of the preferred Colony Stimulating Factors. See the Preferred Drug List (PDL) for the list of preferred Colony Stimulating Factors at: https://papdl.com/preferred-drug-list; AND

8. If a prescription for a Colony Stimulating Factor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Colony Stimulating Factor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Contraceptives, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Contraceptives, Oral must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Contraceptives, Oral at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Contraceptive, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Contraceptives, Oral.

   NOTE: If the beneficiary does not meet the clinical review guideline listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Contraceptive, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Contraceptives, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Contraceptives, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Contraceptive, Other. See the Preferred Drug List (PDL) for the list of preferred Contraceptives, Other at: https://papdl.com/preferred-drug-list.

2. A Contraceptive, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Contraceptive, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Contraceptive, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Contraceptives, Other with the same route of administration AND

2. If a prescription for a Contraceptive, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Contraceptive, Other. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Chronic Obstructive Pulmonary Disease (COPD) Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for COPD Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred COPD Agent. See the Preferred Drug List (PDL) for the list of preferred COPD Agents at: https://papdl.com/preferred-drug-list.

2. A COPD Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. An agent that contains an inhaled glucocorticoid when there is a record of a recent paid claim for another agent that contains an inhaled glucocorticoid in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. An agent that contains an inhaled long-acting anticholinergic when there is a record of a recent paid claim for another agent that contains an inhaled long-acting anticholinergic in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

5. An agent that contains an inhaled long-acting beta agonist when there is a record of a recent paid claim for another agent that contains an inhaled long-acting beta agonist in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a COPD Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Daliresp (roflumilast), all of the following:
   a. Has a diagnosis of severe COPD as documented by medical history, physical exam findings, and lung function testing (forced expiratory volume (FEV1) <50% of predicted) that are consistent with severe COPD according to the current Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines on the diagnosis and management of COPD,
   b. Has a diagnosis of chronic bronchitis as documented by cough and sputum production for at least 3 months in each of 2 consecutive years,
   c. Had other causes of their chronic airflow limitations excluded,
   d. Continues to experience more than 2 exacerbations of COPD per year requiring emergency department visits, hospitalization, or oral steroid use despite one of the following:
i. For a beneficiary with an eosinophil count greater than or equal to 100 cells/microliter, maximum therapeutic doses of or intolerance or contraindication to regular scheduled use of all of the following:

1. Long-acting inhaled beta agonist,
2. Long-acting inhaled anticholinergic,
3. Inhaled corticosteroid

ii. For a beneficiary with an eosinophil count less than 100 cells/microliter, maximum therapeutic doses of or intolerance or contraindication to regular scheduled use of both of the following:

1. Long-acting inhaled beta agonist
2. Long-acting inhaled anticholinergic,

e. Does not have a contraindication to the prescribed medication,

f. Does not have suicidal ideations,

g. One of the following:

i. For a beneficiary with a history of suicide attempt, bipolar disorder, major depressive disorder, schizophrenia, substance use disorder, anxiety disorder, borderline personality disorder, or antisocial personality disorder, was evaluated, treated, and determined to be a candidate for treatment with Daliresp (roflumilast) by a psychiatrist

ii. For all others, had a mental health evaluation performed by the prescriber and determined to be a candidate for treatment with Daliresp (roflumilast);

AND

2. For all other non-preferred COPD Agents, has a history of therapeutic failure, contraindication, or intolerance of the preferred COPD Agents; AND

3. For therapeutic duplication, one of the following:

a. For an inhaled glucocorticoid, is being titrated to or tapered from another inhaled glucocorticoid,

b. For an inhaled long-acting anticholinergic, is being titrated to or tapered from another inhaled long-acting anticholinergic,

c. For an inhaled long-acting beta agonist, is being titrated to or tapered from another inhaled long-acting beta agonist,

d. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

AND
4. If a prescription for a COPD Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR DALIRESP (ROFLUMILAST): The determination of medical necessity of a request for renewal of a prior authorization for a prescription for Daliresp (roflumilast) that was previously approved will take into account whether the beneficiary:

1. Has a documented decrease in the frequency of COPD exacerbations; AND

2. Does not have a contraindication to the prescribed medication; AND

3. Does not have suicidal ideations; AND

4. Was reevaluated and treated for new onset or worsening symptoms of anxiety and depression and determined to continue to be a candidate for treatment with Daliresp (roflumilast); AND

5. If a prescription for Daliresp (roflumilast) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a COPD Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Cytokine and CAM Antagonists

A. Prescriptions That Require Prior Authorization

All prescriptions for Cytokine and CAM Antagonists must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Cytokine and CAM Antagonist, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Cytokine and CAM Antagonist for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed the Cytokine and CAM Antagonist by or in consultation with an appropriate specialist (e.g., gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, genetic specialist, pulmonologist, oncologist, etc.); AND

4. If currently using a different Cytokine and CAM Antagonist, one of the following:
   a. Will discontinue use of that Cytokine and CAM Antagonist prior to starting the requested Cytokine and CAM Antagonist
   b. One of the following:
      i. Has a medical reason for concomitant use of both Cytokine and CAM Antagonists that is supported by peer-reviewed medical literature or national treatment guidelines,
      ii. Is dependent on glucocorticoids in addition to a Cytokine and CAM Antagonist to prevent life-threatening complications,
      iii. Has 2 or more autoimmune or autoinflammatory conditions for which a single Cytokine and CAM Antagonist is not sufficient;

AND

5. Does not have a contraindication to the prescribed medication; AND

6. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

7. For a Cytokine and CAM Antagonist associated with an increased risk of infection according to the FDA-approved package labeling, was evaluated for both of the
following:

a. Active or latent tuberculosis infection documented by results of a tuberculin skin test (purified protein derivative) or blood test (interferon-gamma release assay)
b. Hepatitis B virus infection documented by results of anti-HBs, HBsAg, and anti-HBc;

AND

8. For a Cytokine and CAM Antagonist associated with behavioral and/or mood changes as stated in the FDA-approved package labeling (e.g., Otezla, Siliq), was evaluated for a history of prior suicide attempt, bipolar disorder, or major depressive disorder; AND

9. For treatment of Crohn’s disease, one of the following:

a. Has a diagnosis of moderate to severe Crohn’s disease and one of the following:
   i. Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids
   ii. One of the following:
      a) Failed to maintain remission with a conventional immunomodulator in accordance with current consensus guidelines
      b) Has a contraindication or an intolerance to conventional immunomodulators in accordance with current consensus guidelines

b. Has a diagnosis of Crohn’s disease that is associated with one or more high-risk or poor prognostic feature(s),

c. Both of the following:
   i. Has achieved remission with the requested Cytokine and CAM Antagonist
   ii. Will be using the requested medication as maintenance therapy to maintain remission;

AND

10. For treatment of ulcerative colitis (UC), one of the following:

a. Both of the following:
   i. Has one of the following diagnoses:

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1 e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn’s and Colitis Organization [ECCO]

2 Examples of high-risk or poor prognostic features in patients with Crohn’s disease include initial diagnosis or clinical evidence supports the onset of symptoms at <30 years of age, extensive anatomic involvement, presence of fistula, perianal and/or severe rectal disease, large or deep mucosal lesions on endoscopy or imaging, prior surgical resection, strictureing and/or penetrating behavior, need for steroid therapy at initial diagnosis, extra-intestinal manifestations, laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, high fecal calprotectin levels, severe growth delay (AGA 2014; ECCO 2017; CAG 2019; ECCO-ESPGHAN 2021; AGA 2021).
a) Mild UC that is associated with multiple poor prognostic factors
b) Moderate to severe UC

ii. **One** of the following:

a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids

b) **One** of the following:

i. Failed to maintain remission with a conventional immunomodulator in accordance with current consensus guidelines

(ii) Has a contraindication or an intolerance to conventional immunomodulators in accordance with current consensus guidelines

b. **Both** of the following:

i. Has achieved remission with the requested Cytokine and CAM Antagonist

ii. Will be using the requested medication as maintenance therapy to maintain remission;

**AND**

11. For treatment of moderately to severely active rheumatoid arthritis, has **one** of the following:

a. A history of therapeutic failure of a 3-month trial of a conventional non-biologic disease-modifying antirheumatic drug (DMARD) in accordance with current consensus guidelines

b. A contraindication or an intolerance to conventional non-biologic DMARDs;

**AND**

12. For treatment of juvenile idiopathic arthritis (JIA), **one** of the following:

a. Has **one** of the following:

i. A history of therapeutic failure of a 3-month trial of a conventional non-biologic DMARD

ii. A contraindication or an intolerance to non-biologic DMARDs,

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3 Examples of poor prognostic factors in patients with ulcerative colitis include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).

4 e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn’s and Colitis Organization [ECCO]

5 e.g., American College of Rheumatology [ACR], European League Against Rheumatism [EULAR]
b. Has systemic JIA with active systemic features,\(^6\)

c. Has a diagnosis of JIA that is associated with both of the following:

   i. One or more risk factors\(^7\) for disease severity

   ii. At least one of the following:

      a) Involvement of high-risk joints (e.g., cervical spine, hip, wrist),
      b) High disease activity,
      c) Is at high risk of disabling joint damage as judged by the prescriber,

d. Has active spondililitis and/or enthesitis and one of the following:

   i. A history of therapeutic failure of a 2-week trial of an oral non-steroidal anti-inflammatory drug (NSAID)
   ii. A contraindication or an intolerance to oral NSAIDs;

AND

13. For treatment of adult-onset Still’s disease, one of the following:

   a. Has predominantly systemic disease and one of the following:

      i. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids

      ii. Both of the following:

         a) Has glucocorticoid-dependent Still’s disease
         b) Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid

   b. Has predominantly joint disease and one of the following:

      i. A history of therapeutic failure of a conventional non-biologic DMARD
      ii. A contraindication or an intolerance to conventional non-biologic DMARDs;

AND

14. For treatment of ankylosing spondylitis or other axial spondyloarthritis, has one of the following:

   a. A history of therapeutic failure of a 2-week trial of continuous treatment with 2 different oral NSAIDs (i.e., an oral NSAID taken daily for 2 weeks and a different oral

\(^6\) Active systemic features in patients with JIA include the following: fever, evanescent rash, lymphadenopathy, hepatomegaly, splenomegaly, and serositis (ACR 2013).

\(^7\) Risk factors for disease severity in patients with JIA include positive anti-cyclic citrullinated peptide antibodies, positive rheumatoid factor, presence of joint damage (ACR-AF 2019).
b. A contraindication or an intolerance to oral NSAIDs;
OR an 8-week trial of other topical pharmacologic therapy\textsuperscript{11}

(ii) A contraindication or an intolerance to topical corticosteroids AND other topical pharmacologic therapy

b) Has a history of therapeutic failure of or a contraindication or an intolerance to at least one of the following:

(i) A 3-month trial of conventional systemic therapy\textsuperscript{12}

(ii) Phototherapy;\textsuperscript{13}

AND

17. For treatment of moderate to severe hidradenitis suppurativa (HS), one of the following:

a. For Hurley stage II disease, has a history of therapeutic failure of or a contraindication or an intolerance to both of the following:

a) A 3-month trial of topical clindamycin

b) An adequate trial of a systemic antibiotic\textsuperscript{14}

b. For Hurley stage III disease, one of the following:

i. Has a history of therapeutic failure of or a contraindication or intolerance to an adequate trial of a systemic antibiotic

ii. Is a candidate for or has a history of surgical intervention for HS;

AND

18. For treatment of non-infectious uveitis, one of the following:

a. Has a diagnosis of uveitis associated with JIA or Behçet’s syndrome,

b. Has a history of therapeutic failure of or a contraindication or an intolerance to one of the following:

i. A systemic, topical, intraocular, or periocular corticosteroid

ii. A conventional systemic immunosuppressive,\textsuperscript{15}

c. Both of the following:

i. Has corticosteroid-dependent uveitis\textsuperscript{16}

\textsuperscript{11} e.g., anthralin, calcineurin inhibitors, tar, tazarotene, vitamin D analogs

\textsuperscript{12} e.g., methotrexate, cyclosporine, acitretin

\textsuperscript{13} e.g., NB-UVB, BB-UVB, PUVA, excimer laser, pulsed dye laser, etc.

\textsuperscript{14} e.g., doxycycline, minocycline, or tetracycline; clindamycin; clindamycin + rifampin; rifampin + moxifloxacin + metronidazole; rifampin + levofloxacin + metronidazole; amoxicillin/clavulanate

\textsuperscript{15} e.g., azathioprine, cyclophosphamide, cyclosporine, methotrexate, mycophenolate, tacrolimus

\textsuperscript{16} Corticosteroid-dependent uveitis is defined as requiring a daily systemic corticosteroid dose equivalent to 7.5 mg or greater of prednisone in adults for six weeks or longer.
ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic corticosteroid;

AND

19. For treatment of giant cell arteritis, one of the following:

a. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids,

b. Is at high-risk for glucocorticoid-related complications,

c. Both of the following:
   i. Has glucocorticoid-dependent disease
   ii. Will be using the requested Cytokine and CAM Antagonist with the intent of discontinuing or decreasing the dose of the systemic glucocorticoid;

AND

20. For treatment of familial Mediterranean fever, has one of the following:

a. A history of therapeutic failure of at least a 3-month trial of colchicine at maximally tolerated doses

b. A contraindication or an intolerance to colchicine;

AND

21. For treatment of Behçet’s syndrome, all of the following:

a. Has a diagnosis of Behçet’s syndrome according to current consensus guidelines,\textsuperscript{17}

b. Has recurrent oral ulcers associated with Behçet’s syndrome,

c. Has a history of therapeutic failure of or a contraindication or an intolerance to a topical corticosteroid (e.g., triamcinolone dental paste),

d. Has one of the following:
   i. A history of therapeutic failure of an adequate trial of colchicine at maximally tolerated doses
   ii. A contraindication or an intolerance to colchicine;

AND

22. For treatment of sarcoidosis, both of the following:

a. One of the following:

\textsuperscript{17}\ e.g., EULAR, International Study Group for Behçet’s Disease
i. Has a history of therapeutic failure of or a contraindication or an intolerance to systemic glucocorticoids
ii. Has glucocorticoid-dependent sarcoidosis

b. Has a history of therapeutic failure of or a contraindication or an intolerance to a conventional non-biologic DMARD;

AND

23. For treatment of alopecia areata, both of the following:

a. Has alopecia associated with at least one of the following:
   i. Alopecia universalis,
   ii. Alopecia totalis,
   iii. Greater than 50% scalp involvement,
   iv. Significant disability or impairment of physical, mental, or psychosocial functioning

b. Has a current episode of alopecia areata of greater than 6 months’ duration;

AND

24. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; AND

25. For an oral Janus kinase (JAK) inhibitor, one of the following:

a. Has a history of therapeutic failure of at least one tumor necrosis factor (TNF) blocker or another biologic if recommended for the beneficiary’s diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,

b. Has a contraindication or an intolerance to TNF blockers or other biologics if recommended for the beneficiary’s diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,

c. Has a current history (within the past 90 days) of being prescribed an oral JAK inhibitor;

AND

26. For a non-preferred Cytokine and CAM Antagonist, one of the following:

a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for the beneficiary’s diagnosis

b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Cytokine and CAM Antagonist (does not apply to non-preferred brands when the therapeutically equivalent generic, interchangeable biosimilar, or unbranded biologic is preferred or to non-preferred generics, interchangeable
biosimilars, or unbranded biologics when the therapeutically equivalent brand, interchangeable brand, or brand biologic product is preferred) See the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: https://papdl.com/preferred-drug-list;

AND

27. If a prescription for a Cytokine and CAM Antagonist is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR CYTOKINE AND CAM ANTAGONISTS: The determination of medical necessity of a request for renewal of a prior authorization for a Cytokine and CAM Antagonist that was previously approved will take into account whether the beneficiary:

1. **One** of the following:
   a. Experienced improvement in disease activity and/or level of functioning since initiating therapy with the requested Cytokine and CAM Antagonist
   b. Is prescribed an increased dose or more frequent administration of the requested Cytokine and CAM Antagonist that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

2. Is prescribed the Cytokine and CAM Antagonist by or in consultation with an appropriate specialist (e.g., gastroenterologist, dermatologist, rheumatologist, ophthalmologist, immunologist, genetic specialist, pulmonologist, oncologist, etc.);

AND

3. Is prescribed a dose and duration of therapy that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

4. For a Cytokine and CAM Antagonist associated with behavioral and/or mood changes as stated in the FDA-approved package labeling, was recently reevaluated for behavioral and mood changes as recommended in the FDA-approved package labeling;

AND

5. If a prescription for a Cytokine and CAM Antagonist is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of
drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Cytokine and CAM Antagonist. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References


Crohn's Disease


Psoriatic Arthritis

Psoriasis

Hidradenitis Suppurativa


I. Requirements for Prior Authorization of Dupixent (dupilumab)

A. Prescriptions That Require Prior Authorization

All prescriptions for Dupixent (dupilumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Dupixent (dupilumab), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); **AND**

5. If currently using a different Monoclonal Antibody (MAB) – Anti-IL, Anti-IgE, Anti-TSLP, will discontinue the other MAB – Anti-IL, Anti-IgE, Anti-TSLP prior to starting Dupixent (dupilumab); **AND**

6. For treatment of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of at least **two** of the following OR a contraindication or an intolerance to all of the following:

   a. **One** of the following:
      
      i. For treatment of the face, skin folds, or other critical areas, a 4-week trial of a low-potency topical corticosteroid
      ii. For treatment of other areas, a 4-week trial of a medium-potency or higher topical corticosteroid,

   b. An 8-week trial of a topical calcineurin inhibitor,

   c. Phototherapy in accordance with current consensus guidelines,

   d. Systemic immunosuppressives in accordance with current consensus guidelines (e.g., cyclosporine, azathioprine, methotrexate, mycophenolate mofetil);
AND

7. For a diagnosis of asthma, all of the following:
   
   a. Has asthma severity consistent with the FDA-approved indication for Dupixent (dupilumab) despite maximal therapeutic doses of or intolerance or contraindication to asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma,
   
   b. One of the following:
      
      i. Has absolute blood eosinophil count ≥150 cells/microL
      ii. Is dependent on oral corticosteroids,
   
   c. Will use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

AND

8. For a diagnosis of eosinophilic esophagitis, has a history of therapeutic failure of or a contraindication or an intolerance to a proton pump inhibitor; AND

9. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; AND

10. If a prescription Dupixent (dupilumab) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR DUPIXENT (DUPILUMAB): The determination of medical necessity of a request for renewal of a prior authorization for Dupixent (dupilumab) that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

2. Is prescribed Dupixent (dupilumab) by or in consultation with an appropriate specialist (e.g., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); AND
3. Has documented evidence of improvement in disease severity; **AND**

4. For a diagnosis of asthma, **both** of the following:

   a. **One** of the following:

      i. Has documented measurable evidence of improvement in the severity of the asthma condition
      ii. Has reduction of oral corticosteroid dose while maintaining asthma control

   b. Continues to use Dupixent (dupilumab) in addition to standard asthma controller medications as recommended by current national treatment guidelines;

   **AND**

5. If a prescription Dupixent (dupilumab) is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Dupixent (dupilumab). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **References**


Requirements for Prior Authorization of Enzyme Replacements, Gaucher Disease

A. Prescriptions That Require Prior Authorization

All prescriptions for Enzyme Replacements, Gaucher Disease agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Enzyme Replacement, Gaucher Disease agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Enzyme Replacements, Gaucher Disease agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA) approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Does not have a history of a contraindication to the prescribed medication; AND

5. Is prescribed the Enzyme Replacements, Gaucher Disease agent by or in consultation with a specialist in the treatment of Gaucher disease; AND

6. For a non-preferred Enzyme Replacements, Gaucher Disease agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Enzyme Replacements, Gaucher Disease agents approved or medically accepted for the beneficiary’s indication. See the Preferred Drug List (PDL) for the list of preferred Enzyme Replacements, Gaucher Disease agents at: https://papdl.com/preferred-drug-list; AND

7. For a diagnosis of Gaucher disease, has documentation of both of the following:

   a. One of the following:
   i. Enzyme assay demonstrating a deficiency of beta-glucocerebrosidase (glucosidase) activity
   ii. DNA testing confirming the diagnosis
b. One of the following:
   i. Anemia,
   ii. Bone disease,
   iii. Hepatomegaly,
   iv. Interstitial lung disease,
   v. Splenomegaly,
   vi. Thrombocytopenia;

AND

8. If a prescription for an Enzyme Replacements, Gaucher Disease agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ENZYME REPLACEMENTS, GAUCHER DISEASE AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Enzyme Replacements, Gaucher Disease agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

2. Is prescribed the Enzyme Replacements, Gaucher Disease agent by or in consultation with a specialist in the treatment of Gaucher disease; AND

3. Has documentation of improvement in disease severity since initiating treatment with the requested Enzyme Replacements, Gaucher Disease agent; AND

4. If a prescription for an Enzyme Replacements, Gaucher Disease agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.
C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Enzyme Replacements, Gaucher Disease agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Epinephrine, Self-Injected

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Epinephrine, Self-Injected must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Epinephrine, Self-Injected at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Epinephrine, Self-Injected, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Epinephrine, Self-Injected.

   NOTE: If the beneficiary does not meet the clinical review guideline listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Epinephrine, Self-Injected. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Erythropoiesis Stimulating Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Erythropoiesis Stimulating Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Erythropoiesis Stimulating Agent (ESA), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the ESA for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is prescribed the ESA by or in consultation with an appropriate specialist (e.g., gastroenterologist, hematologist/oncologist, infectious disease specialist, nephrologist, surgeon, etc.); AND

3. Does not have a contraindication to the prescribed ESA; AND

4. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

5. Has been evaluated and treated for other causes of anemia (e.g., iron deficiency, hemolysis, vitamin B12 deficiency, folate deficiency, etc.); AND

6. One of the following:
   a. Has serum ferritin ≥ 100 mcg/L and serum transferrin saturation ≥ 20%
   b. Is receiving supplemental iron therapy;

   AND

7. For a diagnosis of anemia associated with chronic kidney disease, has pretreatment hemoglobin < 10 g/dL; AND

8. For a diagnosis of anemia in cancer patients on chemotherapy, both of the following:
   a. Has pretreatment hemoglobin < 10 g/dL
   b. Is currently receiving myelosuppressive chemotherapy and the anticipated outcome is not cure;

   AND

9. For a diagnosis of anemia due to zidovudine in beneficiaries with HIV infection, all of the following:
   a. Has pretreatment hemoglobin < 10 g/dL,
   b. Has a serum erythropoietin level ≤ 500 mUnits/mL,
c. Is receiving a dose of zidovudine ≤ 4200 mg/week;

AND

10. For a reduction of allogeneic blood transfusion in surgery patients, both of the following:

a. Has pretreatment hemoglobin > 10 to ≤ 13 g/dL
b. Is undergoing elective, noncardiac, nonvascular surgery;

AND

11. For a non-preferred ESA, has a history of therapeutic failure, contraindication, or intolerance of the preferred ESAs approved or medically accepted for the beneficiary's diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ESAs: The determination of medical necessity of a request for renewal of a prior authorization for an ESA that was previously approved will take into account whether the beneficiary:

1. One of the following:
   a. Experienced an increase in hemoglobin compared to baseline
   b. Is prescribed an increased dose of the requested ESA consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

   AND

2. Does not have a contraindication to the prescribed ESA; AND

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. One of the following:
   a. Has serum ferritin ≥ 100 mcg/L and serum transferrin saturation ≥ 20%
   b. Is receiving supplemental iron therapy;

   AND

5. For a diagnosis of anemia associated with chronic renal disease, has one of the following:
   a. Hemoglobin ≤ 10 g/dL for beneficiaries not on dialysis
   b. Hemoglobin ≤ 11 g/dL for beneficiaries on dialysis,

   AND

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6. For a diagnosis of anemia in cancer patients on chemotherapy, has hemoglobin $\leq 12$ g/dL; **AND**

7. For a diagnosis of anemia in zidovudine-treated HIV-infected patients, all of the following:
   a. Has hemoglobin $\leq 12$ g/dL,
   b. Has a serum erythropoietin level $\leq 500$ mUnits/mL,
   c. Is receiving a dose of zidovudine $\leq 4200$ mg/week; **AND**

8. For a non-preferred ESA, has a history of therapeutic failure, contraindication, or intolerance of the preferred ESAs approved or medically accepted for the beneficiary's diagnosis.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Erythropoiesis Stimulating Protein. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **References**

Requirements for Prior Authorization of Estrogens

A. Prescriptions That Require Prior Authorization

Prescriptions for Estrogens that meet any of the following conditions must be prior authorized:

1. A non-preferred Estrogen. See the Preferred Drug List (PDL) for the list of preferred Estrogens at: https://papdl.com/preferred-drug-list.

2. An Estrogen with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Estrogen, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Estrogen for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a history of a contraindication to the prescribed medication; AND

4. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Estrogens; AND

5. For gender dysphoria, both of the following:
   a. Is prescribed the Estrogen by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine
   b. Is prescribed the Estrogen in a manner consistent with the current World Professional Association for Transgender Health standards of care for the health of transsexual, transgender, and gender nonconforming people;

   AND

6. If a prescription for an Estrogen is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to

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meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Estrogen. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

Requirements for Prior Authorization of Fluoroquinolones, Oral

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Fluoroquinolone, Oral must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Fluoroquinolones, Oral at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Fluoroquinolone, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. One of the following:
   a. Has a history of therapeutic failure, intolerance, or contraindication to the preferred Fluoroquinolones, Oral approved or medically accepted for the beneficiary's diagnosis
   b. Has culture and sensitivity test results documenting that only non-preferred Fluoroquinolones, Oral will be effective.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Fluoroquinolone, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of GI Motility, Chronic Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for GI Motility, Chronic Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a GI Motility, Chronic Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the GI Motility, Chronic Agent for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Does not have a contraindication to the prescribed medication; AND

5. One of the following:

   a. For an agent indicated for treatment of a diagnosis involving constipation, has a documented history of therapeutic failure of or a contraindication or an intolerance to two of the following:

      i. Laxatives,
      ii. Fiber supplementation,
      iii. Osmotic agents,
      iv. Bulk forming agents,
      v. Glycerin or bisacodyl suppositories

   b. For an agent indicated for treatment of a diagnosis involving diarrhea, is prescribed the requested medication by or in consultation with a gastroenterologist;

   AND

6. For a non-preferred GI Motility, Chronic Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred GI Motility, Chronic Agents approved or medically accepted for the beneficiary’s diagnosis. See the Preferred Drug List for the list of preferred GI Motility, Chronic Agents at: https://papdl.com/preferred-drug-list; AND

7. If a prescription for a GI Motility, Chronic Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into
account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR GI MOTILITY, CHRONIC AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a GI Motility, Chronic Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the medication; AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a contraindication to the prescribed medication; AND

4. For an agent indicated for treatment of a diagnosis involving diarrhea, is prescribed the requested medication by or in consultation with a gastroenterologist; AND

5. If a prescription for a GI Motility, Chronic Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a GI Motility, Chronic Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy
Requests for prior authorization of Lotronex (alosetron hydrochloride) will be approved as follows:

1. Initial requests will be approved for up to 4 weeks.
2. Renewal requests will be approved for up to 3 months.

E. References

I. Requirements for Prior Authorization of Glucocorticoids, Inhaled

A. Prescriptions That Require Prior Authorization

Prescriptions for Glucocorticoids, Inhaled that meet any of the following conditions must be prior authorized:

1. A non-preferred Glucocorticoid, Inhaled. See the Preferred Drug List (PDL) for the list of preferred Glucocorticoids, Inhaled at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list).

2. A Glucocorticoid, Inhaled with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

3. A Glucocorticoid, Inhaled when there is a record of a recent paid claim for another agent that contains an inhaled glucocorticoid in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

4. An inhaled long-acting anticholinergic when there is a record of a recent paid claim for another inhaled long-acting anticholinergic in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

5. An inhaled long-acting beta agonist when there is a record of a recent paid claim for another agent that contains an inhaled long-acting beta agonist in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Glucocorticoid, Inhaled, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred single-ingredient Glucocorticoid, Inhaled (i.e., a product that contains only one active ingredient), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred single-ingredient Glucocorticoids, Inhaled; **AND**

2. For a non-preferred Glucocorticoid, Inhaled combination agent (i.e., a product that contains more than one active ingredient), has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Glucocorticoid, Inhaled combination agents; **AND**

3. For therapeutic duplication, **one** of the following:
   
   a. For an inhaled glucocorticoid, is being titrated to or tapered from another inhaled glucocorticoid,
   
   b. For an inhaled long-acting anticholinergic, is being titrated to or tapered from another inhaled long-acting anticholinergic,
c. For an inhaled long-acting beta agonist, is being titrated to or tapered from another inhaled long-acting beta agonist,

d. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

4. If a prescription for a Glucocorticoid, Inhaled is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account one of the following:

a. The guidelines set forth in the Quantity Limits Chapter

b. For a formoterol-containing Glucocorticoid, Inhaled for the treatment of asthma, both of the following:

   i. The beneficiary is using the requested medication as part of a therapy that is supported by consensus treatment guidelines [e.g., Single Maintenance and Reliever Therapy (SMART)]

   ii. The prescribed dose is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Glucocorticoid, Inhaled. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Glucocorticoids, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Glucocorticoids, Oral that meet any of the following conditions must be prior authorized:

1. A non-preferred Glucocorticoid, Oral. See the Preferred Drug List (PDL) for the list of preferred Glucocorticoids, Oral at: https://papdl.com/preferred-drug-list.

2. A Glucocorticoid, Oral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Glucocorticoid, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Glucocorticoid, Oral, all of the following:
   
   a. Is prescribed the Glucocorticoid, Oral for a diagnosis that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
   
   b. Is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   
   c. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Glucocorticoids, Oral approved or medically accepted for the beneficiary’s diagnosis

   AND

2. If a prescription for a Glucocorticoid, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Glucocorticoid, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the
prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. **Requirements for Prior Authorization of Growth Hormones**

A. **Prescriptions That Require Prior Authorization**

   All prescriptions for Growth Hormones must be prior authorized.

B. **Review of Documentation for Medical Necessity**

   In evaluating a request for prior authorization of a prescription for a Growth Hormone, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

   1. Is prescribed the Growth Hormone for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

   2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

   3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

   4. Is prescribed the Growth Hormone by an appropriate specialist (e.g., neonatologist [in the neonatal period], endocrinologist, gastroenterologist, or nephrologist); **AND**

   5. Does not have a contraindication to the prescribed medication; **AND**

   6. For a non-preferred Growth Hormone, has a history of therapeutic failure of the preferred Growth Hormones approved or medically accepted for the beneficiary’s diagnosis. See the Preferred Drug List (PDL) for the list of preferred Growth Hormones at: https://papdl.com/preferred-drug-list; **AND**

   7. For a neonate beneficiary, has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., Pediatric Endocrine Society); **AND**

   8. For a pediatric beneficiary, **all** of the following:

      a. For a beneficiary in Tanner stage ≥ 3, a female beneficiary 12 years of age or older, or a male beneficiary 14 years of age or older, has epiphyses that are confirmed as open,

      b. For a diagnosis other than Turner syndrome, Prader Willi syndrome, or short for gestational age (SGA), had appropriate imaging (MRI or CT) of the brain with particular attention to the hypothalamic and pituitary regions to exclude the possibility of a tumor,

      c. Has growth failure that is not due to idiopathic short stature, familial short stature, or constitutional growth delay,
d. Had other causes of short stature excluded,

e. **One** of the following:

i. For a diagnosis of growth hormone deficiency, has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., Pediatric Endocrine Society),

ii. For a diagnosis of insulin-like growth factor-1 (IGF-1) deficiency, **all** of the following:

   a) Has a height > 2.25 standard deviations (SD) below the mean for age or > 2 SD below the mid-parental height percentile,
   
   b) Has a growth velocity < 25th percentile for bone age,
   
   c) Had secondary causes of IGF-1 deficiency excluded (i.e., under-nutrition and hepatic disease),
   
   d) Has a history of having passed growth hormone stimulation tests,

iii. For a diagnosis of chronic renal failure, **both** of the following:

   a) Has a diagnosis of pediatric growth failure, defined as height > 2 SD below the age-related mean, due to chronic renal failure
   
   b) Has not undergone a renal transplant,

iv. For a diagnosis of SGA, **both** of the following:

   a) Was born SGA, defined as having weight or length at birth > 2 SD below the mean or weight below the 10th percentile for gestational age
   
   b) Failed to manifest catch-up growth by 2 years of age, defined as height/length ≥ 2 SD below the mean for age and gender,

v. For a diagnosis of Turner syndrome, Noonan syndrome, or short stature homeobox (SHOX) syndrome, has growth failure defined as height > 2 SD below the age-related mean due to a documented diagnosis of Turner syndrome, Noonan syndrome, or SHOX syndrome,

vi. For a diagnosis of Prader-Willi syndrome, has a documented diagnosis of Prader-Willi syndrome and **both** of the following:

   a) Has growth failure defined as height > 2 SD below the age-related mean
   
   b) **One** of the following:

      (i) Has no symptoms of sleep apnea
      
      (ii) Has a history of sleep apnea or symptoms consistent with sleep apnea and has been fully evaluated and treated;
AND

9. For a beneficiary 18 years of age or older or a beneficiary at any age with closed epiphyses, **all** of the following:

   a. Has a documented history of adult growth hormone deficiency as a result of **one** of the following:

      i. Childhood-onset growth hormone deficiency,
      ii. Pituitary or hypothalamic disease,
      iii. Surgery or radiation therapy,
      iv. Trauma,

   b. Has a diagnosis of growth hormone deficiency confirmed according to the current consensus guidelines (e.g., American Association of Clinical Endocrinologists),

   c. Is currently receiving replacement therapy for any other pituitary hormone deficiencies that is consistent with current medical standards of practice,

   d. For a beneficiary with traumatic brain injury or subarachnoid hemorrhage, has documentation of results of stimulation testing obtained at least 12 months after the date of injury;

AND

10. For the treatment of AIDS-related cachexia, **both** of the following:

   a. **Both** of the following:

      i. Has a diagnosis of wasting syndrome defined by **one** of the following:

         a) A body mass index (BMI) ≤ 18.5

         b) **Both** of the following:

            (i) A BMI ≤ 25

            (ii) An unintentional or unexplained weight loss defined by **one** of the following:

               a. Weight loss of ≥ 10% from baseline premorbid weight
               b. BMI < 20 in the absence of a concurrent illness or medical condition other than HIV infection that would explain these findings

      ii. Has wasting syndrome that is not attributable to other causes, such as depression, *Mycobacterium avium* complex infection, chronic infectious diarrhea, or malignancy (exception: Kaposi’s sarcoma limited to the skin or mucous membranes)
b. Despite a comprehensive AIDS treatment program that includes antiretrovirals, has a history of inadequate response or intolerance to both of the following:

   i. Nutritional supplements that increase caloric and protein intake
   ii. Steroid hormones such as megestrol;

AND

11. If a prescription for a Growth Hormone is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR GROWTH HORMONES: The determination of medical necessity of a request for renewal of a prior authorization for a Growth Hormone that was previously approved will take into account whether the beneficiary:

1. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed the Growth Hormone by an appropriate specialist (e.g., neonatologist [in the neonatal period], endocrinologist, gastroenterologist, or nephrologist); AND

4. Does not have a contraindication to the prescribed medication; AND

5. For a non-preferred Growth Hormone, has a history of therapeutic failure of the preferred Growth Hormones approved or medically accepted for the beneficiary’s diagnosis. See the Preferred Drug List (PDL) for the list of preferred Growth Hormones at: https://papdl.com/preferred-drug-list; AND

6. For a pediatric beneficiary, all of the following:

   a. For a beneficiary in Tanner stage ≥ 3, a female beneficiary 12 years of age or older, or a male beneficiary 14 years of age or older, has epiphyses that are confirmed as open within the previous 6 months,

   b. Demonstrates a growth response ≥ 4 cm per year.
c. Has not reached expected final adult height (defined as mid-parental height),

d. For a diagnosis of Prader-Willi syndrome, demonstrates improvement in **one** of the following since starting the requested medication:

   i. Lean-to-fat body mass  
   ii. Growth velocity;

**AND**

7. For a beneficiary 18 years of age or older or a beneficiary at any age with closed epiphyses, experienced clinical benefit since starting the requested medication as evidenced by **one** of the following:

   a. Increase in total lean body mass,  
   b. Increase in exercise capacity,  
   c. Improved energy level;

**AND**

8. For the treatment of AIDS-related cachexia, demonstrates **one** of the following since starting the requested medication:

   a. Weight stabilization  
   b. Weight increase;

**AND**

9. If the request is for a dose increase, demonstrates compliance with the requested medication; **AND**

10. If a prescription for a Growth Hormone is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

    NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**
Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Growth Hormone. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Growth Hormones will be approved as follows:

1. For the treatment of AIDS-related cachexia:
   a. Initial requests for prior authorization of a Growth Hormone will be approved for up to 6 months.
   b. Renewals of requests for prior authorization of a Growth Hormone will be approved for up to a total of 48 weeks of therapy.

2. For the treatment of short bowel syndrome, approval of requests will be limited to 4 weeks consistent with the FDA-approved package labeling.

3. For all other indications:
   a. Initial requests for prior authorization of a Growth Hormone will be approved for up to 6 months.
   b. Renewal of requests for prior authorization of a Growth Hormone will be approved for up to 12 months.

E. References

5. Management of tissue wasting in patients with HIV infection – UpToDate.
6. 1993 Revised Classification System for HIV Infection and Expanded Surveillance Case Definition for AIDS Among Adolescents and Adults.
Requirements for Prior Authorization of H. Pylori Treatments

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred H. Pylori Treatment must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred H. Pylori Treatments at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred H. Pylori Treatment, the determination of whether the requested prescription is medically necessary will take into account whether:

1. The H. pylori treatment regimens recommended by the American College of Gastroenterology, taken as the individual components and in the same combination, dose, and frequency, cannot be used by the beneficiary because of clinical reasons as documented by the prescriber.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an H. Pylori Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Hepatitis B Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hepatitis B Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hepatitis B Agent. See the Preferred Drug List (PDL) for the list of preferred Hepatitis B Agents at: https://papdl.com/preferred-drug-list.

2. A Hepatitis B Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hepatitis B Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hepatitis B Agent, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatitis B Agents AND

2. If a prescription for a Hepatitis B Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hepatitis B Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Hepatitis C Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hepatitis C Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hepatitis C Agent. See the Preferred Drug List (PDL) for the list of preferred Hepatitis C Agents at: https://papdl.com/preferred-drug-list.

2. A Hepatitis C Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hepatitis C Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hepatitis C Agent, all of the following:
   a. If genotyping is recommended by the American Association for the Study of Liver Diseases (AASLD), has documentation of genotype,
   b. Is prescribed a drug regimen that is consistent with U.S. Food and Drug Administration (FDA)-approved labeling, nationally recognized compendia, or peer-reviewed medical literature,
   c. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   d. Has a cirrhosis assessment documented by a recent noninvasive test (e.g., blood test or imaging, a Fibroscan, FIB-4 calculation, or findings on physical examination),
   e. If the beneficiary has received prior treatment(s) for hepatitis C, documentation of previous hepatitis C treatment regimens,
   f. If resistance-associated substitution (RAS) testing is recommended by the AASLD, has documentation of recommended RAS testing and is prescribed an AASLD-recommended drug regimen based on the documented results of a NS5A RAS screening,
   g. One of the following:
i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hepatitis C Agents appropriate for the beneficiary’s genotype according to peer-reviewed medical literature
ii. Is currently receiving treatment with the same non-preferred Hepatitis C Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

AND

2. If a prescription for a Hepatitis C Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hepatitis C Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Approvals of requests for prior authorization of Hepatitis C Agents will be for the full recommended duration of treatment based on package labeling or consensus treatment guidelines.

E. References

Requirements for Prior Authorization of Hereditary Angioedema (HAE) Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Hereditary Angioedema (HAE) Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an HAE Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the HAE Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is prescribed the HAE Agent by or in consultation with an appropriate specialist (i.e., an allergist/immunologist, hematologist, or dermatologist); **AND**

5. Does not have a history of a contraindication to the prescribed medication; **AND**

6. With the exception of requests for short-term prophylaxis (e.g., surgical or dental procedure), will not be using the requested HAE Agent with another HAE Agent for the same indication (i.e., more than one HAE Agent for acute treatment or more than one HAE Agent for long-term prophylaxis); **AND**

7. For a diagnosis of HAE Type I or II (with C1 inhibitor deficiency/dysfunction), has **both** of the following lab values obtained on two separate instances:

   a. Low C4 complement level (mg/dL)

   b. At least **one** of the following:

      i. Low C1 esterase inhibitor antigenic level (mg/dL)

      ii. Low C1 esterase inhibitor functional level [(<65%) unless already using an androgen or C1 esterase inhibitor];

      **AND**

8. For a diagnosis of HAE Type III (with normal C1 inhibitor), **all** of the following:
a. Has all of the following lab values:
   i. Normal C4 complement level (mg/dL),
   ii. Normal C1 esterase inhibitor antigenic level (mg/dL),
   iii. Normal C1 esterase inhibitor functional level,

b. Has a history of recurrent angioedema without urticaria,

c. One of the following:
   i. Has documentation of a family history of hereditary angioedema
   ii. Has a hereditary angioedema-causing genetic mutation,

d. Failed to respond to maximum recommended doses of antihistamines (e.g., cetirizine 20 mg twice daily);

**AND**

9. Is not taking an estrogen-containing medication unless medically necessary or an ACE inhibitor; **AND**

10. If prescribed the HAE Agent for long-term prophylaxis, has poorly controlled HAE based on the prescriber’s assessment despite use of an HAE Agent for on demand/acute treatment; **AND**

11. For a non-preferred HAE Agent, one of the following:
   a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred HAE Agents approved or medically accepted for the beneficiary’s indication
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred HAE Agent

See the Preferred Drug List (PDL) for the list of preferred HAE Agents at [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list);

**AND**

12. If a prescription for an HAE Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).
NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN HAE AGENT: The determination of medical necessity of a request for renewal of a prior authorization for an HAE agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

2. Is prescribed the HAE Agent by or in consultation with an appropriate specialist (i.e., an allergist/immunologist, hematologist, or dermatologist); **AND**

3. With the exception of requests for short-term prophylaxis, will not be using the requested HAE Agent with another HAE Agent for the same indication (i.e., more than one HAE Agent for acute treatment or more than one HAE Agent for long-term prophylaxis); **AND**

4. If prescribed the HAE Agent for acute treatment, has documentation of a positive clinical response to the requested medication; **AND**

5. If prescribed the HAE Agent for long-term prophylaxis, has a documented reduction in the number of HAE attacks; **AND**

6. If a prescription for an HAE Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an HAE Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
D. References

Requirements for Prior Authorization of Histamine 2 (H2) Receptor Blockers

A. Revisions to Prescriptions That Require Prior Authorization

Prescriptions for H2 Receptor Blockers that meet any of the following conditions must be prior authorized:

1. A non-preferred H2 Receptor Blocker. See the Preferred Drug List (PDL) for the list of preferred H2 Receptor Blockers at: https://papdl.com/preferred-drug-list.

2. An H2 Receptor Blocker with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred H2 Receptor Blocker, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred H2 Receptor Blocker, has a history of therapeutic failure, contraindication, or intolerance to the preferred H2 Receptor Blockers; AND

2. If a prescription for an H2 Receptor Blocker is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an H2 Receptor Blocker. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription.

the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of HIV/AIDS Antiretrovirals

A. Prescriptions That Require Prior Authorization

Prescriptions for HIV/AIDS Antiretrovirals that meet any of the following conditions must be prior authorized:


2. An HIV/AIDS Antiretroviral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A non-nucleoside reverse-transcriptase inhibitor (NNRTI) when there is a record of a recent paid claim for another NNRTI in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

4. A protease inhibitor when there is a record of a recent paid claim for another protease inhibitor (exception: Norvir [ritonavir]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

5. An integrase strand transfer inhibitor when there is a record of a recent paid claim for another integrase strand transfer inhibitor in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

6. A single product regimen when there is a record of a recent paid claim for another single product regimen in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an HIV/AIDS Antiretroviral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred HIV/AIDS Antiretroviral, one of the following:
   
a. Has a current history (within the past 90 days) of being prescribed the same non-preferred HIV/AIDS Antiretroviral (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

b. All of the following:

   i. Has a documented history of contraindication, intolerance, or lab test results showing resistance to the preferred HIV/AIDS Antiretrovirals with the same mechanism of action as the requested agent,
ii. Is prescribed the HIV/AIDS Antiretroviral for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,

iii. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

2. For therapeutic duplication, one of the following:

   a. For an NNRTI, is being transitioned to another NNRTI with the intent of discontinuing one of the medications,
   b. For a protease inhibitor, is being transitioned to another protease inhibitor with the intent of discontinuing one of the medications,
   c. For an integrase strand transfer inhibitor, is being transitioned to another integrase strand transfer inhibitor with the intent of discontinuing one of the medications,
   d. For a single product regimen, is being transitioned to another single product regimen with the intent of discontinuing one of the medications,
   e. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for an HIV/AIDS Antiretroviral is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an HIV/AIDS Antiretroviral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. DHHS Panel on Antiretroviral Guidelines for Adults and Adolescents – A Working Group of the Office of AIDS Research Advisory Council (OARAC). Guidelines for the Use of Antiretroviral Agents in Adults and Adolescents with HIV. Last Updated: December 18, 2019; Last Reviewed: December 18, 2019.
2. DHHS Panel on Antiretroviral Therapy and Medical Management of Children Living with HIV. Guidelines for the Use of Antiretroviral Agents in Pediatric HIV Infection. Last Updated: December 24, 2019; last reviewed December 24, 2019.
Requirements for Prior Authorization of Hypoglycemia Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemia Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemia Treatment. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemia Treatments at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemia Treatment with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemia Treatment, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemia Treatment, cannot use the preferred Hypoglycemia Treatments because of clinical reasons as documented by the prescriber; **AND**

2. If a prescription for a Hypoglycemia Treatment is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemia Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Hypoglycemics, Incretin Mimetics/Enhancers

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Incretin Mimetics/Enhancers that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Incretin Mimetic/Enhancer. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Incretin Mimetic/Enhancers at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemic, Incretin Mimetic/Enhancer with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A glucagon-like peptide-1 (GLP-1) receptor agonist when there is a record of a recent paid claim for another GLP-1 receptor agonist or a dipeptidyl peptidase 4 (DPP-4) inhibitor in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. A DPP-4 inhibitor when there is a record of a recent paid claim for another DPP-4 inhibitor or a GLP-1 receptor agonist in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Incretin Mimetic/Enhancer, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Incretin Mimetic/Enhancer, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Incretin Mimetics/Enhancers with the same mechanism of action approved or medically accepted for the beneficiary’s diagnosis; AND

2. For therapeutic duplication of a GLP-1 receptor agonist or a DPP-4 inhibitor, one of the following:
   a. Is being transitioned to or from another GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the medications
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

3. If a prescription for a Hypoglycemic, Incretin Mimetic/Enhancer is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary...
necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Incretin Mimetic/Enhancer. If the applicable guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the applicable guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Hypoglycemics, Meglitinides

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Meglitinides that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Meglitinide. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Meglitinides at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list).

2. A Hypoglycemic, Meglitinide with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm](http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Meglitinide, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Meglitinide, has history of therapeutic failure, contraindication, or intolerance to the preferred Hypoglycemic, Meglitinides; **AND**

2. If a prescription for a Hypoglycemic, Meglitinide is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Meglitinide. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Hypoglycemics, Alpha-Glucosidase Inhibitors

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Alpha-Glucosidase Inhibitors that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Alpha-Glucosidase Inhibitor. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Alpha-Glucosidase Inhibitors at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemic, Alpha-Glucosidase Inhibitor with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Alpha-Glucosidase Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Alpha-Glucosidase Inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Alpha-Glucosidase Inhibitors AND

2. If a prescription for a Hypoglycemic, Alpha-Glucosidase Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Alpha-Glucosidase Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

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I. Requirements for Prior Authorization of Hypoglycemics, Insulin and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Insulin and Related Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Insulin and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Insulin and Related Agents at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemic, Insulin and Related Agent combination agent that contains a glucagon-like peptide-1 (GLP-1) receptor agonist with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A glucagon-like peptide-1 (GLP-1) receptor agonist when there is a record of a recent paid claim for another GLP-1 receptor agonist or a dipeptidyl peptidase 4 (DPP-4) inhibitor in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Insulin and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Insulin and Related Agent that does not contain a glucagon-like peptide-1 (GLP-1) receptor agonist, both of the following:
   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Insulin and Related Agents with the same duration of action
   b. Has a history of contraindication or intolerance to the preferred Hypoglycemics, Insulin and Related Agents that would not be expected to occur with the requested medication;

   **AND**

2. For a non-preferred Hypoglycemic, Insulin and Related Agent that contains a GLP-1 receptor agonist, both of the following:
   a. Has a clinical reason why a preferred basal insulin and a preferred GLP-1 receptor agonist cannot be used
   b. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Insulin and Related Agents that contain a GLP-1 receptor agonist;

   **AND**
3. For Afrezza (insulin human inhalation powder), all of the following:
   a. Is prescribed Afrezza (insulin human inhalation powder) for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,
   b. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   c. Is prescribed Afrezza (insulin human inhalation powder) by or in consultation with an endocrinologist,
   d. Does not have a contraindication to the prescribed medication;

AND

4. For therapeutic duplication of a GLP-1 receptor agonist, one of the following:
   a. Is being transitioned to or from another GLP-1 receptor agonist or DPP-4 inhibitor with the intent of discontinuing one of the medications
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

5. If a prescription for a Hypoglycemic, Insulin and Related Agent combination agent that contains a GLP-1 receptor agonist is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AFREZZA (insulin human inhalation powder): The determination of medical necessity of a request for renewal of a prior authorization for Afrezza (insulin human inhalation powder) that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response to the medication as documented by a decrease in hemoglobin A1c; AND
2. Is prescribed Afrezza (insulin human inhalation powder) by or in consultation with an endocrinologist; AND
3. Does not have a contraindication to the prescribed medication.
NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Insulin and Related Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Hypoglycemics, Metformins

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Metformins that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Metformin. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Metformins at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemic, Metformin with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Metformin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Metformin, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Metformins AND

2. If a prescription for a Hypoglycemic, Metformin is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Metformin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Hypoglycemics, SGLT2 Inhibitors

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, SGLT2 Inhibitors that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, SGLT2 Inhibitor. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, SGLT2 Inhibitors at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemic, SGLT2 Inhibitor with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A Hypoglycemic, SGLT2 Inhibitor when there is a record of a recent paid claim for another Hypoglycemic, SGLT2 Inhibitor in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, SGLT2 Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, SGLT2 Inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, SGLT2 Inhibitors approved or medically accepted for the beneficiary’s diagnosis; AND

2. For therapeutic duplication, one of the following:
   a. Is being transitioned to or from another Hypoglycemic, SGLT2 Inhibitor with the intent of discontinuing one of the medications
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

   AND

3. If a prescription for a Hypoglycemic, SGLT2 Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

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Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, SGLT2 Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Hypoglycemics, Sulfonylureas

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, Sulfonylureas that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, Sulfonylurea. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, Sulfonylureas at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemic, Sulfonylurea with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, Sulfonylurea, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, Sulfonylurea, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, Sulfonylureas AND

2. If a prescription for a Hypoglycemic, Sulfonylurea is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, Sulfonylurea. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Hypoglycemics, TZDs

A. Prescriptions That Require Prior Authorization

Prescriptions for Hypoglycemics, TZDs that meet any of the following conditions must be prior authorized:

1. A non-preferred Hypoglycemic, TZD. See the Preferred Drug List (PDL) for the list of preferred Hypoglycemics, TZDs at: https://papdl.com/preferred-drug-list.

2. A Hypoglycemic, TZD with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A Hypoglycemic, TZD when there is a record of a recent paid claim for another Hypoglycemic, TZD in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hypoglycemic, TZD, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Hypoglycemic, TZD, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Hypoglycemics, TZDs; AND

2. For therapeutic duplication, one of the following:
   a. Is being transitioned to or from another Hypoglycemic, TZD with the intent of discontinuing one of the medications
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines; AND

3. If a prescription for a Hypoglycemic, TZD is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process
Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hypoglycemic, TZD. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Immunomodulators, Atopic Dermatitis

A. Prescriptions That Require Prior Authorization

Prescriptions for Immunomodulators, Atopic Dermatitis that meet the following conditions must be prior authorized:

1. A non-preferred Immunomodulator, Atopic Dermatitis. See Preferred Drug List (PDL) for the list of preferred Immunomodulators, Atopic Dermatitis at: https://papdl.com/preferred-drug-list.

2. An Immunomodulator, Atopic Dermatitis with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A topical phosphodiesterase type 4 (PDE4) inhibitor.

4. A topical Janus kinase (JAK) inhibitor.

5. A targeted systemic Immunomodulator, Atopic Dermatitis (e.g., Adbry [tralokinumab], Cibinbo [abrocitinib], Rinoq [upadacitinib]).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Immunomodulator, Atopic Dermatitis, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Dupixent (dupilumab), see the prior authorization guidelines related to Dupixent (dupilumab); OR

2. Is prescribed the Immunomodulator, Atopic Dermatitis for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

3. Is age-appropriate according to FDA-approved package labeling, national compendia, or peer-reviewed medical literature; AND

4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

5. Does not have a contraindication to the requested medication; AND

6. For a non-preferred topical calcineurin inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical calcineurin inhibitors; AND

7. For a topical PDE4 inhibitor, both of the following:
a. Has a history of therapeutic failure of or a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary’s diagnosis
b. Has a history of therapeutic failure of or a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary’s diagnosis;

**AND**

8. For a topical JAK inhibitor, **both** of the following:

a. Has a history of therapeutic failure of or a contraindication or an intolerance to a 4-week trial of a topical corticosteroid approved or medically accepted for the treatment of the beneficiary’s diagnosis
b. Has a history of therapeutic failure of or a contraindication or an intolerance to an 8-week trial of a topical calcineurin inhibitor approved or medically accepted for the treatment of the beneficiary’s diagnosis;

**AND**

9. For all other non-preferred topical Immunomodulators, Atopic Dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary’s diagnosis; **AND**

10. For a targeted systemic Immunomodulator, Atopic Dermatitis, **all** of the following:

   a. Is prescribed the targeted systemic Immunomodulator, Atopic Dermatitis by or in consultation with an appropriate specialist (e.g., dermatologist),

   b. For treatment of moderate to severe chronic atopic dermatitis, has a history of therapeutic failure of at least **two** of the following OR a contraindication or an intolerance to **all** of the following:

      i. **One** of the following:

         a) For treatment of the face, skin folds, or other critical areas, a 4-week trial of a low-potency topical corticosteroid
         b) For treatment of other areas, a 4-week trial of a medium-potency or higher topical corticosteroid,

      ii. An 8-week trial of a topical calcineurin inhibitor,

      iii. Phototherapy in accordance with current consensus guidelines,

      iv. Conventional systemic immunosuppressives in accordance with current consensus guidelines (e.g., azathioprine, cyclosporine, methotrexate, mycophenolate mofetil),

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c. For treatment of all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first-line therapy(ies) if applicable according to current consensus treatment guidelines,

d. For an oral JAK inhibitor, one of the following:

i. Has a history of therapeutic failure of at least one biologic if recommended for the beneficiary’s diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,

ii. Has a contraindication or an intolerance to other biologics if recommended for the beneficiary’s diagnosis in the FDA-approved package labeling for the requested oral JAK inhibitor,

iii. Has a current history (within the past 90 days) of being prescribed an oral JAK inhibitor,

e. For a non-preferred targeted systemic Immunomodulator, Atopic Dermatitis, one of the following:

i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred targeted systemic Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary’s diagnosis

ii. Has a current history (within the past 90 days) of being prescribed the same targeted systemic Immunomodulator, Atopic Dermatitis;

AND

11. If a prescription for an Immunomodulator, Atopic Dermatitis is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR AN IMMUNOMODULATOR, ATOPIC DERMATITIS: The determination of medical necessity of a request for renewal of a prior authorization for an Immunomodulator, Atopic Dermatitis that was previously approved will take into account whether the beneficiary:

1. Has documented evidence of improvement of disease severity; AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a contraindication to the requested medication; AND

4. For a non-preferred topical calcineurin inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical calcineurin inhibitors; AND

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5. For all other non-preferred topical Immunomodulators, Atopic Dermatitis, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical Immunomodulators, Atopic Dermatitis approved or medically accepted for the beneficiary’s diagnosis; **AND**

6. For a targeted systemic Immunomodulator, Atopic Dermatitis, is prescribed the targeted systemic Immunomodulator, Atopic Dermatitis by or in consultation with an appropriate specialist (e.g., dermatologist); **AND**

7. If a prescription for an Immunomodulator, Atopic Dermatitis is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**C. Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Immunomodulator, Atopic Dermatitis. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

**D. References**


I. Requirements for Prior Authorization of Immunomodulators, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for a non-preferred Immunomodulator, Topical must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Immunomodulators, Topical at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Immunomodulator, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Immunomodulators, Topical.

   NOTE: If the beneficiary does not meet the clinical review guideline listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Immunomodulator, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Immunosuppressives, Oral

A. Prescriptions That Require Prior Authorization

Prescriptions for Immunosuppressives, Oral that meet any of the following conditions must be prior authorized:

1. A non-preferred Immunosuppressive, Oral. See the Preferred Drug List (PDL) for the list of preferred Immunosuppressives, Oral at: https://papdl.com/preferred-drug-list.

2. An Immunosuppressive, Oral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Immunosuppressive, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Immunosuppressive, Oral for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a contraindication to the requested medication; AND

4. For Lupkynis (voclosporin), all of the following:
   a. For the treatment of lupus nephritis, has a diagnosis of active lupus nephritis that is confirmed by a kidney biopsy unless a kidney biopsy is not medically advisable,
   b. Is prescribed Lupkynis (voclosporin) by or in consultation with an appropriate specialist (e.g., nephrologist, rheumatologist),
   c. Is prescribed Lupkynis (voclosporin) in combination with background immunosuppressive therapy as tolerated,
   d. Is not prescribed Lupkynis (voclosporin) in combination with cyclophosphamide or Benlysta (belimumab); AND

5. For all other non-preferred Immunosuppressives, Oral, one of the following:
   a. Has a documented history of therapeutic failure of or a contraindication or an
intolerance to the preferred Immunosuppressives, Oral approved or medically accepted for the beneficiary’s diagnosis
b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Immunosuppressive, Oral;

AND

6. If a prescription for an Immunosuppressive, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Immunosuppressive, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

Requirements for Prior Authorization of Intra-Articular Hyaluronates

A. **Prescriptions That Require Prior Authorization**

All prescriptions for Intra-Articular Hyaluronates must be prior authorized.

B. **Review of Documentation for Medical Necessity**

In evaluating a request for prior authorization of a prescription for an Intra-Articular Hyaluronate, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Intra-Articular Hyaluronate for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication; **AND**

2. Has a documented history of therapeutic failure, contraindication, or intolerance to all of the following:
   
   a. Non-pharmacologic treatments,
   b. Acetaminophen or non-steroidal anti-inflammatory drugs (NSAIDs),
   c. Intra-articular glucocorticoid injection;

   **AND**

3. Does not have a contraindication to the requested agent; **AND**

4. For a non-preferred Intra-Articular Hyaluronate, has a history of therapeutic failure, contraindication, or intolerance of the preferred Intra-Articular Hyaluronates. See the Preferred Drug List (PDL) for the list of preferred Intra-Articular Hyaluronates at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list); **AND**

5. If a prescription for an Intra-Articular Hyaluronate is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

   **NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR INTRA-ARTICULAR HYALURONATES: The determination of medical necessity of a request for renewal of a prior authorization for an Intra-Articular Hyaluronate that was previously approved will take into account whether the beneficiary:

January 5, 2021
1. Has documented improvement in pain or joint function following the first treatment; **AND**

2. Did not receive an Intra-Articular Hyaluronate in the same joint within the past 6 months; **AND**

3. Does not have a contraindication to the requested agent; **AND**

4. If a prescription for an Intra-Articular Hyaluronate is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**B. Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Intra-Articular Hyaluronate. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

**C. Revisions to Dose and Duration of Therapy**

Requests for prior authorization of an Intra-Articular Hyaluronate will be approved for one treatment course per knee.

**D. References**

Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT) 
11. Orthovisc prescribing information. Anika Therapeutics, Inc.
Requirements for Prior Authorization of Intranasal Rhinitis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Intranasal Rhinitis Agents that meet the following conditions must be prior authorized:

1. A non-preferred Intranasal Rhinitis Agent. See the Preferred Drug List (PDL) for the list of preferred Intranasal Rhinitis Agents at: https://papdl.com/preferred-drug-list.

2. An Intranasal Rhinitis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. An Intranasal Rhinitis Agent containing an antihistamine when there is a record of a recent paid claim for another Intranasal Rhinitis Agent containing an antihistamine in DHS' Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

4. An Intranasal Rhinitis Agent containing a steroid when there is a record of a recent paid claim for another Intranasal Rhinitis Agent containing a steroid in DHS' Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

EXEMPTION FROM PRIOR AUTHORIZATION: Triamcinolone acetonide nasal spray is exempt from prior authorization when prescribed for a child under four (4) years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Intranasal Rhinitis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Intranasal Rhinitis Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Intranasal Rhinitis Agents with the same mechanism of action; AND

2. For therapeutic duplication, one of the following:
   a. Is being titrated to or tapered from another Intranasal Rhinitis Agent containing an agent with the same mechanism of action
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines; AND

3. If a prescription for an Intranasal Rhinitis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.
C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Intranasal Rhinitis Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Automated Prior Authorization

Prior authorization of a prescription for a non-preferred Intranasal Rhinitis Agent with a prescribed quantity that does not exceed the quantity limit established by DHS will be automatically approved when the Point-of-Sale On-Line Claims Adjudication System verifies a record of a paid claim(s) within 365 days prior to the date of service that documents that the guidelines to determine medical necessity listed in Section B. have been met.
Requirements for Prior Authorization of Iron Chelating Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Iron Chelating Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Iron Chelating Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication;  **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;  **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;  **AND**

4. Is prescribed the Iron Chelating Agent by or in consultation with a specialist (i.e., hematologist);  **AND**

5. Has documentation of baseline lab results as recommended in the FDA-approved package labeling;  **AND**

6. Does not have a history of a contraindication to the prescribed medication;  **AND**

7. For a non-preferred Iron Chelating Agent, has documented therapeutic failure, contraindication, or intolerance of the preferred Iron Chelating Agents approved or medically accepted for the beneficiary’s diagnosis. See the Preferred Drug List (PDL) for the list of preferred Iron Chelating Agents at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR IRON CHELATING AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Iron Chelating Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication;  **AND**

2. Is prescribed the Iron Chelating Agent by or in consultation with a specialist (i.e., hematologist);  **AND**

3. Has documentation of results of recent lab monitoring as recommended in the FDA-approved package labeling;  **AND**

4. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package
labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

5. Is continuing treatment with the prescribed Iron Chelating Agent based on recent lab results as recommended in the FDA-approved package labeling.

   **NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Iron Chelating Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **References**

Requirements for Prior Authorization of Hematopoietic Mixtures

A. Prescriptions That Require Prior Authorization

Prescriptions for Hematopoietic Mixtures that meet any of the following conditions must be prior authorized:

1. A non-preferred Hematopoietic Mixture. See the Preferred Drug List (PDL) for the list of preferred Hematopoietic Mixtures at: https://papdl.com/preferred-drug-list.

2. A Hematopoietic Mixture with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Hematopoietic Mixture, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Hematopoietic Mixture, has a history of therapeutic failure, contraindication, or intolerance to the preferred Hematopoietic Mixtures; AND

2. If a prescription for a Hematopoietic Mixture is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Hematopoietic Mixture. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Iron, Parenteral

A. Prescriptions That Require Prior Authorization

Prescriptions for Irons, Parenteral that meet any of the following conditions must be prior authorized:

1. A non-preferred Iron, Parenteral. See the Preferred Drug List (PDL) for the list of preferred Irons, Parenteral at: https://papdl.com/preferred-drug-list.

2. An Iron, Parenteral with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Iron, Parenteral, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Iron, Parenteral, has a history of therapeutic failure, contraindication, or intolerance to the preferred Irons, Parenteral; AND

2. If a prescription for an Iron, Parenteral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Iron, Parenteral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Leukotriene Modifiers

A. Prescriptions That Require Prior Authorization

Prescriptions for Leukotriene Modifiers that meet any of the following conditions must be prior authorized:

1. A non-preferred Leukotriene Modifier. See the Preferred Drug List (PDL) for the list of preferred Leukotriene Modifiers at: https://papdl.com/preferred-drug-list.

2. A Leukotriene Modifier with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A Leukotriene Modifier when there is a record of a recent paid claim for another Leukotriene Modifier in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

EXEMPTION FROM PRIOR AUTHORIZATION: Montelukast pediatric granules are exempt from prior authorization when prescribed for a child under 2 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Leukotriene Modifier, the determination of whether the prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Leukotriene Modifier, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Leukotriene Modifiers; AND

2. For therapeutic duplication, one of the following:
   a. Is being transitioned to or from another Leukotriene Modifier with the intent of discontinuing one of the medications
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

   AND

3. If a prescription for a Leukotriene Modifier is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.
C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Leukotriene Modifier. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Lipotropics, Other

A. Prescriptions That Require Prior Authorization

Prescriptions for Lipotropics, Other that meet any of the following conditions must be prior authorized:

1. A non-preferred Lipotropic, Other. See the Preferred Drug List (PDL) for the list of preferred Lipotropics, Other at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list).

2. A Lipotropic, Other with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

3. A proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor (e.g., Leqvio [inclisiran], Praluent [alirocumab], Repatha [evolocumab]).

4. An adenosine triphosphate-citrate lyase (ACL) inhibitor (e.g., Nexletol [bempedoic acid], Nexlizet [bempedoic acid/ezetimibe]).

5. A microsomal triglyceride transfer protein (MTP) inhibitor (e.g., Juxtapid [lomitapide]).

6. An angiopoietin-like 3 (ANGPTL3) inhibitor (e.g., Evkeeza [evinacumab]).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Lipotropic, Other, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the requested Lipotropic, Other for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. For treatment of a lipid disorder, has documentation of results of a lipid profile within 3 months prior to the request for the Lipotropic, Other; **AND**

6. For a PCSK9 inhibitor, **all** of the following:
a. Has at least one of the following:

   i. A history of clinical atherosclerotic cardiovascular disease (ASCVD),
   
i. A diagnosis of familial hypercholesterolemia in accordance with current consensus guidelines,
   
i. A diagnosis of other severe hypercholesterolemia (baseline [before treatment with any lipid-lowering agent] LDL-C ≥190 mg/dL),

b. Has a history of one of the following:

   i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with maximally tolerated doses of 2 different high-intensity statins for ≥3 consecutive months each,

   ii. Both of the following:

      a) A temporally related intolerance to 2 high-intensity statins that occurred after both of the following:

         (i) Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber as clinically indicated (e.g., hypothyroidism, vitamin D deficiency)

         (ii) All possible drug interactions with statins were addressed by all of the following (if clinically appropriate):

               a. Dose decrease of the interacting non-statin drug,
               b. Discontinuation of the interacting non-statin drug,
               c. Change to an alternative statin that has a lower incidence of drug interactions

      b) One of the following:

         (i) Therapeutic failure while adherent to treatment for ≥3 consecutive months with the lowest FDA-approved daily dose or alternate-day dosing of any statin
         (ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,

   iii. A contraindication to statins,

   c. Has one of the following:

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1 Clinical ASCVD consists of acute coronary syndromes, history of myocardial infarction, stable or unstable angina or coronary or other arterial revascularization, stroke, transient ischemic attack, or peripheral artery disease including aortic aneurysm, all of atherosclerotic origin. (American Heart Association 2018 Cholesterol Clinical Practice Guidelines)

2 e.g., American Heart Association, International Familial Hypercholesterolaemia Foundation, European Atherosclerosis Society, International Atherosclerosis Society

3 Temporally related intolerance of a statin is defined as the occurrence of symptoms and/or lab abnormalities upon initiation of a statin, resolution of symptoms and/or lab abnormalities upon discontinuation of a statin, and recurrence of symptoms and/or lab abnormalities after rechallenge with the same statin at the same dose.
i. A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,

ii. A contraindication or an intolerance to ezetimibe,

iii. An LDL-C that is >25% above goal LDL-C while adherent to treatment with the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,

d. Is prescribed the requested PCSK9 inhibitor in addition to one of the following:

   i. For treatment of homozygous familial hypercholesterolemia (HoFH), standard lipid-lowering treatments as recommended by current consensus guidelines

   ii. For treatment of all other conditions, the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),

e. If currently using a different PCSK9 inhibitor, will discontinue use of that PCSK9 inhibitor prior to starting the requested PCSK9 inhibitor,

f. For a non-preferred PCSK9 inhibitor, has one of the following:

   i. A history of therapeutic failure of at least 1 preferred PCSK9 inhibitor approved or medically accepted for the beneficiary’s diagnosis

   ii. A contraindication or an intolerance to the preferred PCSK9 inhibitors approved or medically accepted for the beneficiary’s diagnosis;

AND

7. For an ACL inhibitor, all of the following:

   a. Is prescribed the ACL inhibitor by or in consultation with an appropriate specialist (e.g., cardiologist, endocrinologist, or other provider specializing in lipid disorders),

   b. Has at least one of the following:

      i. A history of clinical ASCVD,

      ii. A diagnosis of familial hypercholesterolemia in accordance with current consensus guidelines,

      iii. A diagnosis of other severe hypercholesterolemia (baseline [before treatment with any lipid-lowering agent] LDL-C ≥190 mg/dL),

   c. Has a history of one of the following:

      i. Failure to achieve goal LDL-C or percentage reduction of LDL-C while adherent to treatment with maximally tolerated doses of 2 different high-intensity statins for ≥3 consecutive months each,

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4 e.g., American Heart Association/American College of Cardiology, American Association of Clinical Endocrinologists/American College of Endocrinology, American Diabetes Association, National Lipid Association, European Society of Cardiology/European Atherosclerosis Society, International Familial Hypercholesterolaemia Foundation, International Atherosclerosis Society
ii. **Both** of the following:

   a) A temporally related intolerance to 2 high-intensity statins that occurred after **both** of the following:

      (i) Modifiable comorbid conditions that may enhance statin intolerance were ruled out and/or addressed by the prescriber as clinically indicated (e.g., hypothyroidism, vitamin D deficiency)

      (ii) All possible drug interactions with statins were addressed by **all** of the following (if clinically appropriate):

         a. Dose decrease of the interacting non-statin drug,
         b. Discontinuation of the interacting non-statin drug,
         c. Change to an alternative statin that has a lower incidence of drug interactions

   b) **One** of the following:

      (i) Therapeutic failure while adherent to treatment for ≥3 consecutive months with the lowest FDA-approved daily dose or alternate-day dosing of any statin

      (ii) A temporally related intolerance to the lowest FDA-approved daily dose or alternate-day dosing of any statin,

   iii. A contraindication to statins,

   d. Has **both** of the following:

   i. **One** of the following:

      a) A history of therapeutic failure of while adherent to treatment with ezetimibe in combination with the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months,

      b) A contraindication or an intolerance to ezetimibe,

      c) An LDL-C that is >25% above goal LDL-C while adherent to treatment with the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate) for ≥3 consecutive months

   ii. **One** of the following:

      a) A history of therapeutic failure of while adherent to treatment with a PCSK9 inhibitor

      b) A contraindication or an intolerance to PCSK9 inhibitors,

   e. Is prescribed the requested ACL inhibitor in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),
f. If currently taking simvastatin or pravastatin, will not be using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

**AND**

8. For an ANGPTL3 inhibitor or MTP inhibitor, **all** of the following:

   a. Is prescribed the requested medication by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders,

   b. For treatment of HoFH, has a diagnosis of HoFH in accordance with current consensus guidelines,

   c. **One** of the following:
      
      i. Has a history of therapeutic failure of or a contraindication or an intolerance to PCSK9 inhibitors
      ii. Is homozygous for LDL receptor (LDLR)-negative mutations (i.e., has LDLR-negative mutations in both alleles) associated with LDLR activity below 2%,

   d. Is prescribed the requested medication in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

**AND**

9. For icosapent ethyl, **all** of the following:

   a. **One** of the following:
      
      i. Has a history of clinical ASCVD,

      ii. **Both** of the following:

         a) Has diabetes mellitus
         b) Has 2 additional ASCVD risk factors (e.g., age ≥50 years, cigarette smoking, hypertension, HDL-C ≤40 mg/dL for males or ≤50 mg/dL for females, hs-CRP >3.00 mg/L, CrCl <60 mL/min, retinopathy, micro- or macroalbuminuria, ABI <0.9]),

      iii. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary’s diagnosis,

   b. Has fasting triglycerides ≥150 mg/dL,

   c. Has one of the following:
i. A history of therapeutic failure of while adherent to treatment with maximally tolerated doses of 2 different statins for ≥3 consecutive months each,
ii. A history of statin intolerance after modifiable risk factors have been addressed,
iii. A contraindication to statins;

AND

10. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary’s diagnosis; AND

11. If a prescription for a Lipotropic, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR LIPOTOPICS, OTHER: The determination of medical necessity of a request for renewal of a prior authorization for a Lipotropic, Other that was previously approved will take into account whether the beneficiary:

1. Has documentation of a positive clinical response demonstrated by lab test results, if appropriate for the diagnosis, since starting the requested medication (e.g., decreased LDL-C, decreased triglycerides, etc.); AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a contraindication to the prescribed medication; AND

4. For a PCSK9 inhibitor, is using the requested PCSK9 inhibitor in addition to one of the following:
   a. For treatment of HoFH, standard lipid-lowering treatments as recommended by current consensus guidelines5
   b. For treatment of all other conditions, the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate);

   AND

5. For an ACL inhibitor, all of the following:

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5 e.g., American Heart Association/American College of Cardiology, American Association of Clinical Endocrinologists/American College of Endocrinology, American Diabetes Association, National Lipid Association, European Society of Cardiology/European Atherosclerosis Society, International Familial Hypercholesterolaemia Foundation, International Atherosclerosis Society
a. Is prescribed the ACL inhibitor by or in consultation with an appropriate specialist (e.g., cardiologist, endocrinologist, or other provider specializing in lipid disorders),
b. Is using the requested ACL inhibitor in addition to the maximally tolerated dose of the highest-tolerated intensity statin (if clinically appropriate),
c. If currently taking simvastatin or pravastatin, is not using the requested ACL inhibitor concomitantly with simvastatin at a dose of >20 mg daily or pravastatin at a dose of >40 mg daily;

AND

6. For an ANGPTL3 inhibitor or MTP inhibitor, both of the following:
   a. Is prescribed the requested medication by or in consultation with a cardiologist, endocrinologist, or other provider specializing in lipid disorders
   b. Is using the requested medication in addition to standard lipid-lowering treatments as recommended by current consensus guidelines;

AND

7. For icosapent ethyl, experienced a decrease in fasting triglycerides since starting icosapent ethyl; AND

8. For all other non-preferred Lipotropics, Other, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Other approved or medically accepted for the beneficiary’s diagnosis;

AND

9. If a prescription for a Lipotropic, Other is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Lipotropics, Other. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy
Requests for prior authorization of Lipotropics, Other will be approved as follows:

1. For a PCSK9 inhibitor:
   a. Initial requests will be approved for up to 3 months.
   b. Renewal requests will be approved for up to 12 months.

2. For an ACL inhibitor:
   a. Initial requests will be approved for up to 3 months.
   b. Renewal requests will be approved for up to 12 months.

3. For all other Lipotropics, Other:
   a. Initial requests will be approved for up to 6 months.
   b. Renewal requests will be approved for up to 12 months.

E. References


Inherited Dyslipidemias


Non-Statin Medications


Statin Intolerance


I. Requirements for Prior Authorization of Lipotropics, Statins

A. Prescriptions That Require Prior Authorization

Prescriptions for Lipotropics, Statins that meet any of the following conditions must be prior authorized:

1. A non-preferred Lipotropic, Statin. See the Preferred Drug List (PDL) for the list of preferred Lipotropics, Statins at: https://papdl.com/preferred-drug-list.

2. A Lipotropic, Statin with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A Lipotropic, Statin when there is a record of a recent paid claim for another Lipotropic, Statin in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Lipotropic, Statin the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Lipotropic, Statin, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Lipotropics, Statins; AND

2. For therapeutic duplication, one of the following:
   a. Is being transitioned to or from another Lipotropic, Statin with the intent of discontinuing one of the medications
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines; AND

3. If a prescription for a Lipotropic, Statin is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a
Lipotropic, Statin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Local Anesthetics, Topical

A. Prescriptions That Require Prior Authorization

Prescriptions for Local Anesthetics, Topical that meet any of the following conditions must be prior authorized:

1. A non-preferred Local Anesthetic, Topical. See the Preferred Drug List (PDL) for the list of preferred Local Anesthetics, Topical at: https://papdl.com/preferred-drug-list.

2. Oral viscous lidocaine solution and oral lidocaine jelly when prescribed for a beneficiary under 3 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Local Anesthetic, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Local Anesthetic, Topical, has a history of therapeutic failure, intolerance, or contraindication of the preferred Local Anesthetics, Topical; AND

2. For oral viscous lidocaine solution and oral lidocaine jelly when prescribed for a beneficiary under 3 years of age, all of the following:
   a. Is not prescribed oral viscous lidocaine solution or oral lidocaine jelly for the treatment of teething pain,
   b. For all other indications, has documented therapeutic failure, contraindication, or intolerance of alternative recommended treatments for the beneficiary’s indication,
   c. Is prescribed a dose that is consistent with U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section C. above to assess the medical necessity of a prescription for a Local Anesthetic, Topical. If the guidelines in Section C. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician
reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Monoclonal Antibodies – Anti-IL, Anti-IgE, Anti-TSLP (MABs – Anti-IL, Anti-IgE, Anti-TSLP)

A. Prescriptions That Require Prior Authorization

All prescriptions for MABs – Anti-IL, Anti-IgE, Anti-TSLP must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Dupixent (dupilumab), see the prior authorization guidelines related to Dupixent (dupilumab); OR

2. Is prescribed the MAB – Anti-IL, Anti-IgE, Anti-TSLP for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

3. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

5. Is prescribed the MAB – Anti-IL, Anti-IgE, Anti-TSLP by or in consultation with an appropriate specialist (i.e., pulmonologist, allergist, immunologist, dermatologist, hematologist/oncologist, rheumatologist, etc.); AND

6. If currently using a different MAB – Anti-IL, Anti-IgE, Anti-TSLP than requested, will discontinue the other MAB – Anti-IL, Anti-IgE, Anti-TSLP prior to starting the requested agent; AND

7. For a non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP, one of the following:
   a. Has a history of therapeutic failure of or an intolerance or a contraindication of the preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP approved or medically accepted for the beneficiary’s indication
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP

   See the Preferred Drug List for the list of preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP at: https://papdl.com/preferred-drug-list;

   AND

8. For a diagnosis of asthma, both of the following:

   a. Has a history of therapeutic failure of or an intolerance or a contraindication of the preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP approved or medically accepted for the beneficiary’s indication
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred MAB – Anti-IL, Anti-IgE, Anti-TSLP

See the Preferred Drug List for the list of preferred MABs – Anti-IL, Anti-IgE, Anti-TSLP at: https://papdl.com/preferred-drug-list;
a. Has an asthma severity that is consistent with the FDA-approved indication for the prescribed MAB – Anti-IL, Anti-IgE, Anti-TSLP despite maximal therapeutic doses of or intolerance or contraindication to standard asthma controller medications based on current national treatment guidelines for the diagnosis and management of asthma.
b. Will use the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in addition to standard asthma controller medications as recommended by current national treatment guidelines for the diagnosis and management of asthma.

AND

9. For a diagnosis of chronic idiopathic urticaria, both of the following:
   a. Has a history of urticaria for a period of at least 6 weeks
   b. One of the following:
      i. Requires systemic steroids to control urticarial symptoms
      ii. Has a history of therapeutic failure of or a contraindication or an intolerance to maximum tolerated doses of an H1 antihistamine taken for at least 2 weeks;

AND

10. For a diagnosis of eosinophilic granulomatosis with polyangiitis (EGPA), all of the following:
   a. Has a diagnosis of EGPA supported by all of the following:
      i. A history of asthma,
      ii. A history of absolute blood eosinophil count $\geq$1000 cells/microL or blood eosinophil level $>$10% of leukocytes,
      iii. A history of at least one of the following:
         a) Histopathological evidence of one of the following:
            (i) Eosinophilic vasculitis,
            (ii) Perivascular eosinophilic infiltration,
            (iii) Eosinophil-rich granulomatous inflammation,
         b) Neuropathy, mono or poly (motor deficit or nerve conduction abnormality),
         c) Pulmonary infiltrates, non-fixed,
         d) Sino-nasal abnormality,
         e) Cardiomyopathy,
         f) Glomerulonephritis,
         g) Alveolar hemorrhage,
         h) Palpable purpura,
i) Positive test for ANCA,

b. **One** of the following:
   
   i. Requires systemic glucocorticoids to maintain remission
   ii. Has a contraindication or an intolerance to systemic glucocorticoids,

   c. For a beneficiary with severe EGPA as defined by national treatment guidelines, has a history of therapeutic failure of or a contraindication or an intolerance to rituximab or cyclophosphamide;

   **AND**

11. For a diagnosis of hypereosinophilic syndrome (HES), **all** of the following:

   a. Has documented FIP1L1-PDGFRA-negative HES with organ damage or dysfunction,

   b. Has a blood eosinophil count $\geq 1000$ cells/microL,

   c. **One** of the following:
      
      i. Requires or has required systemic glucocorticoids to maintain remission
      ii. Has a contraindication or an intolerance to systemic glucocorticoids;

   **AND**

12. For all other diagnoses, has a history of therapeutic failure of or a contraindication or an intolerance to first line therapy(ies) if applicable according to consensus treatment guidelines; **AND**

13. For Xolair (omalizumab) for a diagnosis of asthma, has a diagnosis of allergen-induced asthma (allergic asthma confirmed by either a positive skin test or radioallergosorbent test) to an unavoidable perennial aeroallergen (e.g., pollen, mold, dust mite, etc.); **AND**

14. For Cinqair (reslizumab) for a diagnosis of asthma with an eosinophilic phenotype, has an absolute blood eosinophil count $\geq 400$ cells/microL; **AND**

15. For Nucala (mepolizumab) for a diagnosis of asthma, has asthma with an eosinophilic phenotype with absolute blood eosinophil count $\geq 150$ cells/microL; **AND**

16. For Fasenra (benralizumab), has asthma with an eosinophilic phenotype with absolute blood eosinophil count $\geq 150$ cells/microL; **AND**

17. If a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available
NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR MABs – ANTI-IL, ANTI-IgE, ANTI-TSLP: The determination of medical necessity of a request for renewal of a prior authorization for a MAB – Anti-IL, Anti-IgE, Anti-TSLP that was previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

2. Is prescribed a MAB – Anti-IL, Anti-IgE, Anti-TSLP by or in consultation with an appropriate specialist (i.e., pulmonologist, allergist, immunologist, dermatologist, rheumatologist, etc.); **AND**

3. Is not using the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in combination with another MAB – Anti-IL, Anti-IgE, Anti-TSLP; **AND**

4. For a diagnosis of asthma, **both** of the following:
   a. Has measurable evidence of improvement in the severity of the asthma condition
   b. Continues to use the requested MAB – Anti-IL, Anti-IgE, Anti-TSLP in addition to standard asthma controller medications as recommended by current national treatment guidelines for the diagnosis and management of asthma;

   **AND**

5. For a diagnosis of chronic idiopathic urticaria, **both** of the following:
   a. Experienced improvement of symptoms
   b. Has a documented rationale for continued use;

   **AND**

6. For a diagnosis of HES or EGPA, has **one** of the following:
   a. Measurable evidence of improvement in disease activity
   b. Reduction in use of systemic glucocorticoids for this indication;

   **AND**

7. If a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary
will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a MAB – Anti-IL, Anti-IgE, Anti-TSLP. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References


15. Fasenra (benralizumab) [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals; October 2019.


Requirements for Prior Authorization of Macrolides

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Macrolide must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Macrolides at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Macrolide, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. One of the following:
   a. Has a history of therapeutic failure, intolerance, or contraindication to the preferred Macrolides approved or medically accepted for the beneficiary’s diagnosis
   b. Has culture and sensitivity test results documenting that only non-preferred Macrolides will be effective.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Macrolide. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Macular Degeneration Agents

A. **Prescriptions That Require Prior Authorization**

All prescriptions for Macular Degeneration Agents must be prior authorized.

B. **Review of Documentation for Medical Necessity**

In evaluating a request for prior authorization of a prescription for a Macular Degeneration Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is prescribed the medication by a retinal specialist; **AND**

3. **One** of the following:
   
a. Has a history of therapeutic failure, intolerance, or contraindication to intravitreal bevacizumab
   b. Cannot use intravitreal bevacizumab because of medical reasons as documented by the prescriber (e.g., beneficiary has neovascular (wet) age-related macular degeneration);

4. Is prescribed a dose and frequency that is consistent with FDA-approved package labeling or nationally recognized compendia or is medically accepted; **AND**

5. For a non-preferred Macular Degeneration Agent, has a history of therapeutic failure, intolerance, or contraindication of the preferred Macular Degeneration Agents approved or medically accepted for the beneficiary's diagnosis. See the Preferred Drug List (PDL) for the list of preferred Macular Degeneration Agents at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list); **AND**

6. If a prescription for a Macular Degeneration Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm](http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm).

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.
FOR RENEWALS OF PRIOR AUTHORIZATION FOR MACULAR DEGENERATION AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Macular Degeneration Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed the medication by a retinal specialist; AND

2. Has documentation of previous date(s) of administration; AND

3. Has documentation of tolerability and a positive clinical response based on the prescriber’s assessment; AND

4. Is prescribed a dose and frequency that is consistent with FDA-approved package labeling or nationally recognized compendia or is medically accepted; AND

5. If a prescription for a Macular Degeneration Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: [http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm](http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Macular Degeneration Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References


I. Requirements for Prior Authorization of Methotrexate

A. Prescriptions That Require Prior Authorization

Prescriptions for Methotrexate that meet any of the following conditions must be prior authorized:

1. A non-preferred Methotrexate. See the Preferred Drug List (PDL) for the list of preferred Methotrexates at: https://papdl.com/preferred-drug-list.

2. A Methotrexate with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Methotrexate, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Methotrexate, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Methotrexates AND

2. If a prescription for a Methotrexate is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Methotrexate. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Multiple Sclerosis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Multiple Sclerosis Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Multiple Sclerosis Agent. See the Preferred Drug List (PDL) for the list of preferred Multiple Sclerosis Agents at: https://papdl.com/preferred-drug-list.

2. A prescription for Ampyra (dalfampridine ER), Aubagio (teriflunomide), Gilenya (fingolimod), Tysabri (natalizumab), or Tecfidera (dimethyl fumarate DR).

3. A Multiple Sclerosis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Multiple Sclerosis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Tysabri (natalizumab), see the policy related to Tysabri (natalizumab); OR

2. For Zeposia (ozanimod), see the policy related to Zeposia (ozanimod); OR

3. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; AND

4. Is prescribed the Multiple Sclerosis Agent by one of the following:
   a. For Ampyra (dalfampridine ER), a neurologist or physical medicine and rehabilitation (PM&R) specialist
   b. For all other Multiple Sclerosis Agents, a neurologist;

   AND

5. Does not have a contraindication to the prescribed Multiple Sclerosis Agent; AND

6. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

7. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature; AND

8. For a non-preferred Multiple Sclerosis Agent, one of the following:
a. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Multiple Sclerosis Agents approved for the beneficiary’s diagnosis

b. **One** of the following:

   i. Has a current prescription (within the past 90 days) for the same non-preferred Multiple Sclerosis Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

   ii. For a non-preferred Multiple Sclerosis Agent with a dosing interval exceeding 90 days (e.g., Lemtrada, Mavenclad, Ocrevus), is receiving treatment with the same non-preferred Multiple Sclerosis Agent and will continue therapy at a dosing interval supported by FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature;

**AND**

9. For Ampyra (dalfampridine ER), has motor dysfunction on a continuous basis that impairs the ability to complete instrumental activities of daily living or activities of daily living; **AND**

10. For Mavenclad (cladribine), has documentation of a recent lymphocyte count within recommended limits according to FDA-approved package labeling before initiating the first treatment course; **AND**

11. If a prescription for a Multiple Sclerosis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**FOR RENEWALS OF PRIOR AUTHORIZATION FOR MULTIPLE SCLEROSIS AGENTS:**

The determination of medical necessity of a request for renewal of a prior authorization for a Multiple Sclerosis Agent that was previously approved will take into account whether the beneficiary:

1. Is prescribed the Multiple Sclerosis Agent by **one** of the following:

   a. For Ampyra (dalfampridine ER), a neurologist or PM&R specialist
   b. For all other Multiple Sclerosis Agents, a neurologist;

   **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Does not have a contraindication to the prescribed Multiple Sclerosis Agent; **AND**

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4. **One** of the following:

   a. For Ampyra (dalfampridine ER), has a documented improvement in motor function

   b. For all other Multiple Sclerosis Agents, **one** of the following:

      i. For a Multiple Sclerosis Agent prescribed for a diagnosis of a relapsing form of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course

      ii. For a Multiple Sclerosis Agent prescribed for a diagnosis of primary progressive multiple sclerosis, based on the prescriber’s professional judgement, continues to benefit from the prescribed Multiple Sclerosis Agent;

      **AND**

5. For Lemtrada (alemtuzumab), received the previous treatment course at least 12 months prior to the requested treatment course with Lemtrada (alemtuzumab); **AND**

6. For Mavenclad (cladribine), **both** of the following:

   a. Has documentation of a recent lymphocyte count within recommended limits according to FDA-approved package labeling before initiating the second treatment course

   b. Has not exceeded the recommended total number of treatment courses according to FDA-approved package labeling;

   **AND**

7. If a prescription for a Multiple Sclerosis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

    NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

   Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Multiple Sclerosis Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Dose and Duration of Therapy**
Requests for prior authorization of Multiple Sclerosis Agents will be approved as follows:

1. For Ampyra (dalfampridine ER) or Aubagio (teriflunomide):
   a. Initial requests will be approved for up to 3 months.
   b. Renewal requests will be approved for up to 6 months.

2. For Lemtrada (alemtuzumab):
   a. Requests for an initial treatment course will be approved for up to 5 days.
   b. Requests for subsequent treatment courses will be approved for up to 3 days.

3. For Mavenclad (cladribine):
   a. Requests for prior authorization will be approved for a duration of therapy consistent with FDA-approved package labeling.

E. References:


Requirements for Prior Authorization of Neuropathic Pain Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Neuropathic Pain Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Neuropathic Pain Agent. See the Preferred Drug List (PDL) for the list of preferred Neuropathic Pain Agents at: https://papdl.com/preferred-drug-list.

2. A Neuropathic Pain Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. A prescription for a gabapentinoid when there is a record of a recent paid claim for another gabapentinoid in the Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Neuropathic Pain Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. For Gralise (gabapentin extended-release), has a history of therapeutic failure, contraindication, or intolerance to both of the following:

   a. Tricyclic antidepressants
   b. Regular-release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day);

   AND
4. For Horizant (gabapentin enacarbil), one of the following:

   a. For a diagnosis of postherpetic neuralgia, has a documented history of therapeutic failure, intolerance, or contraindication to both of the following:

      i. Tricyclic antidepressants
      ii. Regular-release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)

   b. For a diagnosis of moderate-to-severe primary restless leg syndrome, has a documented history of therapeutic failure, intolerance, or contraindication to both of the following:

      i. Regular-release gabapentin (titrated to maximal tolerated effective dose of 1800 mg/day)
      ii. One of the following:

         a) Pramipexole
         b) Ropinirole;

   AND

5. For all other non-preferred Neuropathic Pain Agents, has a history of therapeutic failure, contraindication, or intolerance of the preferred Neuropathic Pain Agents approved or medically accepted for the beneficiary’s diagnosis; AND

6. For a Neuropathic Pain Agent that is subject to the U.S. Drug Enforcement Agency (DEA) Controlled Substances Act (i.e., controlled substance), has documentation that the prescriber or the prescriber’s delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary’s controlled substance prescription history; AND

7. For therapeutic duplication of a gabapentinoid, one of the following:

   a. Is being titrated to or tapered from another gabapentinoid
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;
AND

8. If a prescription for a Neuropathic Pain Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR NEUROPATHIC PAIN AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Neuropathic Pain Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication; AND

2. For a Neuropathic Pain Agent that is subject to the DEA Controlled Substances Act (i.e., controlled substance), has documentation that the prescriber or the prescriber’s delegate conducted a search of the PDMP for the beneficiary’s controlled substance prescription history; AND

3. If a prescription for a Neuropathic Pain Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Neuropathic Pain Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
D. References

I. Requirements for Prior Authorization of Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

A. Prescriptions That Require Prior Authorization

Prescriptions for NSAIDs that meet any of the following conditions must be prior authorized:

1. A non-preferred NSAID. See the Preferred Drug List (PDL) for the list of preferred NSAIDs at: https://papdl.com/preferred-drug-list.

2. A prescription for oral or nasal ketorolac when more than a 5-day supply is prescribed in the past 90 days.

3. An NSAID with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

4. An NSAID when there is a record of a recent paid claim for another NSAID in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an NSAID, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For oral or nasal ketorolac, all of the following:
   a. Is age-appropriate according to U.S. Food and Drug Administration (FDA)-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   b. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature,
   c. Is not concurrently taking aspirin or any other NSAIDs;
   AND

2. For a non-preferred NSAID, one of the following:
   a. Both of the following:
      i. For a non-preferred oral NSAID, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred oral NSAIDs (excluding ketorolac)
      ii. For a non-preferred oral NSAID combination drug with more than one active ingredient (e.g., Duexis, Vimovo, etc.), has a clinical reason as documented by the prescriber why the individual active ingredients cannot be used concurrently,
   b. For a non-preferred topical NSAID, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred topical NSAIDs,
c. For non-preferred nasal ketorolac, has a clinical reason as documented by the prescriber why oral ketorolac cannot be used,

d. For all other non-preferred non-oral NSAIDs, **one** of the following:

   i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred NSAIDs
   ii. Has a clinical reason as documented by the prescriber why the routes of administration of the preferred NSAIDs cannot be used;

**AND**

3. For therapeutic duplication, **one** of the following:

   a. Is being transitioned to another drug in the same class with the intent of discontinuing one of the medications
   b. Has a medical reason for concurrent use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

**AND**

4. If a prescription for an NSAID is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an NSAID. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **References**

Requirements for Prior Authorization of Oncology Agents, Breast Cancer

A. Prescriptions That Require Prior Authorization

Prescriptions for Oncology Agents, Breast Cancer that meet any of the following conditions must be prior authorized:

1. A non-preferred Oncology Agent, Breast Cancer. See the Preferred Drug List (PDL) for the list of preferred Oncology Agents, Breast Cancer at: https://papdl.com/preferred-drug-list.

2. A prescription for letrozole.

3. An Oncology Agent, Breast Cancer with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacieservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Oncology Agent, Breast Cancer, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred agent, has a history of therapeutic failure, contraindication, or intolerance to the preferred Oncology Agents, Breast Cancer; AND

2. For letrozole, is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding use to promote fertility. The requesting prescriber must provide documentation from the medical record of the diagnosis; AND

3. If a prescription for an Oncology Agent, Breast Cancer is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Oncology Agent, Breast Cancer. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
D. References:

2. Femara (letrozole) Package Insert, Novartis January 2014
I. Requirements for Prior Authorization of Obesity Treatment Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Obesity Treatment Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Obesity Treatment Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a request for Evekeo (amphetamine) for any indication other than the treatment of obesity, see the prior authorization guidelines related to Stimulants and Related Agents; OR

2. For beneficiaries 18 years of age and older, one of the following:
   a. Has a body mass index (BMI) greater than or equal to 30 kg/m²
   b. Both of the following:
      i. One of the following:
         a) Has a BMI greater than or equal to 27 kg/m² and less than 30 kg/m²
         b) Has been determined by the prescriber to be a candidate for treatment based on degree of adiposity, waist circumference, history of bariatric surgery, BMI exceptions for the beneficiary’s ethnicity, etc.
      ii. Has at least one weight-related comorbidity as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, obstructive sleep apnea, metabolic syndrome, etc.;

      AND

3. For beneficiaries less than 18 years of age, one of the following:
   a. Has a BMI in the 95th percentile or greater standardized for age and sex based on current Centers for Disease Control and Prevention (CDC) charts
   b. Both of the following:
      i. One of the following:
         a) Has a BMI in the 85th percentile or greater standardized for age and sex based on current CDC charts
         b) Has been determined by the prescriber to be a candidate for treatment based on degree of adiposity, history of bariatric surgery, etc.
ii. Has at least one weight-related comorbidity as determined by the prescriber, such as dyslipidemia, hypertension, type 2 diabetes, prediabetes, obstructive sleep apnea, metabolic syndrome, etc.;

AND

4. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); AND

5. Is age- and weight-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

6. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

7. Does not have a contraindication to the prescribed medication; AND

8. For an Obesity Treatment Agent that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance), has documentation that the prescriber or the prescriber’s delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary’s controlled substance prescription history; AND

9. For Evekeo (amphetamine), all of the following:
   a. Was assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider,
   b. Has documentation that the beneficiary has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,
   c. For a beneficiary with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances,
   d. Both of the following:
      i. Has a history of trial and failure of or a contraindication or an intolerance to all other Obesity Treatment Agents (preferred and non-preferred)
      ii. Has documentation from prescriber explaining the rationale for why the requested medication is needed and plan for tapering;

AND

10. For all other non-preferred Obesity Treatment Agents, has history of therapeutic failure of or a contraindication or an intolerance to the preferred Obesity Treatment Agents approved or medically accepted for the beneficiary’s diagnosis or indication. See the Preferred Drug
List for the list of preferred Obesity Treatment Agents at: https://papdl.com/preferred-drug-list; AND

11. For therapeutic duplication, one of the following:
   a. For a glucagon-like peptide-1 (GLP-1) receptor agonist, is being titrated to or tapered from a dipeptidyl peptidase-4 (DPP-4) inhibitor or another GLP-1 receptor agonist,
   b. For a stimulant agent, is being titrated to or tapered from another stimulant agent,
   c. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

AND

12. If a prescription for an Obesity Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR OBESITY TREATMENT AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for an Obesity Treatment Agent that was previously approved will take into account whether the beneficiary:

1. For beneficiaries 18 years of age and older, one of the following:
   a. Is continuing with dose titration and experiencing a positive response to therapy,
   b. Experienced a percent reduction of baseline body weight that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose,
   c. Continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber’s assessment;

AND

2. For beneficiaries less than 18 years of age, one of the following:
   a. Is continuing with dose titration and experiencing a positive response to therapy,
   b. Experienced a percent reduction of baseline BMI or BMI z-score that is consistent with the recommended cutoff in FDA-approved package labeling, peer-reviewed medical literature, or consensus treatment guidelines after 3 months of therapy with the maximum recommended/tolerated dose,
c. Continues to experience clinical benefit from the Obesity Treatment Agent based on the prescriber’s assessment;

**AND**

3. Has been counseled about lifestyle changes and behavioral modification (e.g., healthy diet and increased physical activity); **AND**

4. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

5. Does not have a contraindication to the prescribed medication; **AND**

6. For an Obesity Treatment Agent that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance), has documentation that the prescriber or the prescriber’s delegate conducted a search of the Pennsylvania PDMP for the beneficiary’s controlled substance prescription history; **AND**

7. For Evekeo (amphetamine), both of the following:
   a. For a beneficiary with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances
   b. Has documentation from prescriber explaining rationale for why the requested medication continues to be needed and plan for tapering;

**AND**

8. For all other non-preferred Obesity Treatment Agents, has history of therapeutic failure of or a contraindication or an intolerance to the preferred Obesity Treatment Agents approved or medically accepted for the beneficiary’s diagnosis or indication. See the Preferred Drug List for the list of preferred Obesity Treatment Agents at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list); **AND**

9. For therapeutic duplication, one of the following:
   a. For a GLP-1 receptor agonist, is being titrated to or tapered from a DPP-4 inhibitor or another GLP-1 receptor agonist,
   b. For a stimulant agent, is being titrated to or tapered from another stimulant agent,
   c. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

**AND**

10. If a prescription for an Obesity Treatment Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Obesity Treatment Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Dose and Duration of Therapy**

Requests for prior authorization of Obesity Treatment Agents will be approved as follows:

1. For Evekeo (amphetamine), all requests will be approved for up to 3 months.

2. For a GLP-1 receptor agonist (e.g., Saxenda or Wegovy), all requests will be approved for up to 6 months.

3. For all other Obesity Treatment Agents:
   a. Initial requests for prior authorization will be approved for up to 4 months.
   b. Renewals of requests for prior authorization will be approved for up to 6 months.

E. **References**


Requirements for Prior Authorization of Oncology Agents, Oral

A. Prescriptions That Require Prior Authorization
All prescriptions for Oncology Agents, Oral must be prior authorized

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Oncology Agent, Oral, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary

1. Is prescribed the Oncology Agent, Oral for the treatment of a diagnosis that is indicated in the U.S Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND
2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature;

AND

Is prescribed the Oncology Agent, Oral by or in consultation with an oncologist or hematologist

AND

For a non-preferred Oncology Agent, Oral, one of the following:
   a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Oncology Agents, Oral approved or medically accepted for the beneficiary’s diagnosis
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Oncology Agent, Oral

See the Preferred Drug List (PDL) for the list of preferred Oncology Agents, Oral at: https://papdl.com/preferred-drug-list;

AND

1. If the prescription for an Oncology Agent, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines that are set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ONCOLOGY AGENTS, ORAL:
The determination of medical necessity of a request for renewal of a prior
authorization for an Oncology Agent, Oral that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication;  
   AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling,  
   Nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed the Oncology Agent, Oral by or in consultation with an oncologist or hematologist; AND

4. If a prescription for an Oncology Agent, Oral is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:
   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Oncology Agent, Oral. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Ophthalmics, Allergic Conjunctivitis

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Ophthalmic, Allergic Conjunctivitis must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Allergic Conjunctivitis at: https://papdl.com/preferred-drug-list.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Ophthalmic, Allergic Conjunctivitis, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Ophthalmics, Allergic Conjunctivitis.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Ophthalmic, Allergic Conjunctivitis. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Ophthalmics, Antibiotics

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Ophthalmic, Antibiotic must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Antibiotics at: https://papdl.com/preferred-drug-list.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Ophthalmic, Antibiotic, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

- Has a history of therapeutic failure, contraindication, or intolerance to the preferred Ophthalmics, Antibiotics approved or medically accepted for the beneficiary’s diagnosis.

  NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Ophthalmic, Antibiotic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Ophthalmics, Antibiotic-Steroid Combinations

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Ophthalmic, Antibiotic-Steroid Combination must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Antibiotic-Steroid Combinations at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Ophthalmic, Antibiotic-Steroid Combination, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Ophthalmics, Antibiotic-Steroid Combinations.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Ophthalmic, Antibiotic-steroid combinations. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Ophthalmics, Glaucoma

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Ophthalmic, Glaucoma must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Glaucoma at: https://papdl.com/preferred-drug-list.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Ophthalmic, Glaucoma, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of therapeutic failure, **contraindication**, or intolerance to the preferred Ophthalmics, Glaucoma.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Ophthalmic, Glaucoma. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Dry Eye Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for Dry Eye Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred Dry Eye Treatment. See the Preferred Drug List (PDL) for the list of preferred Dry Eye Treatments at: https://papdl.com/preferred-drug-list.

2. A Dry Eye Treatment with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Dry Eye Treatment, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Dry Eye Treatment, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Dry Eye Treatments AND

2. If a prescription for a Dry Eye Treatment is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Dry Eye Treatment. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Ophthalmics, Anti-Inflammatories

A. Prescriptions That Require Prior Authorization

Prescriptions for Ophthalmics, Anti-Inflammatories that meet any of the following conditions must be prior authorized:

1. A non-preferred Ophthalmics, Anti-Inflammatory. See the Preferred Drug List (PDL) for the list of preferred Ophthalmics, Anti-Inflammatories at: https://papdl.com/preferred-drug-list.

2. An Ophthalmics, Anti-Inflammatory with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Ophthalmics, Anti-Inflammatory, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Ophthalmics, Anti-Inflammatory, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Ophthalmics, Anti-Inflammatories approved or medically accepted for the beneficiary’s diagnosis; AND

2. If a prescription for an Ophthalmics, Anti-Inflammatory is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Ophthalmics, Anti-Inflammatory. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Opioid Use Disorder Treatments

A. Prescriptions That Require Prior Authorization

Prescriptions for Opioid Use Disorder Treatments that meet any of the following conditions must be prior authorized:

1. A non-preferred Opioid Use Disorder Treatment. See the Preferred Drug List (PDL) for the list of preferred Opioid Use Disorder Treatments at: https://papdl.com/preferred-drug-list.

2. An Opioid Use Disorder Treatment with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

REMINDER: A prescription for a benzodiazepine, opioid analgesic, controlled substance sedative hypnotic, or carisoprodol requires prior authorization when a beneficiary has a concurrent prescription for a buprenorphine Opioid Use Disorder Treatment. Refer to the specific individual handbook chapters (e.g., Analgesics, Opioid Long-Acting, Analgesics, Opioid Short-Acting, Anticonvulsants, Anxiolytics, Skeletal Muscle Relaxants, Sedative Hypnotics) for corresponding prior authorization guidelines.

REMINDER: A prescription for an opioid analgesic requires prior authorization when a beneficiary has a concurrent prescription for Vivitrol.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Opioid Use Disorder Treatment, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Opioid Use Disorder Treatment for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. For Lucemyra (lofexidine), is prescribed a dose and duration of therapy that are consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. For a non-preferred Opioid Use Disorder Treatment, one of the following:
   a. For a sublingual buprenorphine Opioid Use Disorder Treatment, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred sublingual buprenorphine Opioid Use Disorder Treatments,
   b. For an alpha-2 adrenergic agonist Opioid Use Disorder Treatment, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred alpha-2 adrenergic agonist Opioid Use Disorder Treatments,
   c. For a non-sublingual buprenorphine Opioid Use Disorder Treatment, has a history of
therapeutic failure of or a contraindication or an intolerance to the preferred non-
sublingual buprenorphine Opioid Use Disorder Treatments;

AND

4. If a prescription for an Opioid Use Disorder Treatment is for a quantity that exceeds the
quantity limit, the determination of whether the prescription is medically necessary will
also take into account the guidelines set forth in the Quantity Limits Chapter; AND

5. For a diagnosis of Opioid Use Disorder, if a prescription for a sublingual buprenorphine
Opioid Use Disorder Treatment is for a daily dose that exceeds 24 mg/day, all of the
following:

   a. Whether the beneficiary is prescribed a daily dose consistent with medically
      accepted prescribing practices and standards of care,
   b. Whether the beneficiary has an unsatisfactory clinical response (e.g., uncontrolled
      withdrawal or cravings) at the current quantity limit,
   c. For a beneficiary already established on buprenorphine, whether the beneficiary has a
      recent urine drug screen that is positive for buprenorphine and norbuprenorphine.

NOTE: If the beneficiary does not meet the clinical review guidelines and quantity limit
guidelines listed above but, in the professional judgment of the physician reviewer, the
services are medically necessary to meet the medical needs of the beneficiary, the
request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the
clinical guidelines in Section B. above to assess the medical necessity of a prescription for
an Opioid Use Disorder Treatment. If the guidelines in Section B. are met, the reviewer will
prior authorize the prescription. If the guidelines are not met, the prior authorization request
will be referred to a physician reviewer for a medical necessity determination. Such a request
for prior authorization will be approved when, in the professional judgment of the physician
reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. Dose and Duration of Therapy

Requests for prior authorization of Lucemyra (lofexidine) will be approved
for a dose and duration of therapy consistent with the FDA-approved package labeling,
nationally recognized compendia, or peer-reviewed medical literature.

E. References

Systematic Review and Critical Appraisal of Guidelines for Chronic Pain.” Annals of Internal Medicine,
Volume 160, Number 1 (January 7, 2014).


Requirements for Prior Authorization of Opioid Overdose Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for non-preferred Opioid Overdose Agents must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Opioid Overdose Agents at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Opioid Overdose Agent, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. Has a history of contraindication or intolerance to the preferred Opioid Overdose Agents.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an Opioid Overdose Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Otic Antibiotics

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Otic Antibiotic must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Otic Antibiotics at: https://papdl.com/preferred-drug-list.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Otic Antibiotic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure, intolerance, or contraindication to the preferred Otic Antibiotics approved or medically accepted for the beneficiary’s diagnosis.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Otic Antibiotic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Pulmonary Hypertension Agents, Oral and Inhaled

A. Prescriptions That Require Prior Authorization

All prescriptions for Pulmonary Hypertension Agents, Oral and Inhaled must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Pulmonary Hypertension Agent, Oral and Inhaled, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **One** of the following:
   a. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication, excluding use to treat sexual or erectile dysfunction
   b. For the treatment of pulmonary arterial hypertension (PAH), is prescribed a Pulmonary Hypertension Agent, Oral and Inhaled that is appropriate for the beneficiary’s level of risk based on current risk calculator assessment (e.g., REVEAL 2.0) and current medical literature;

   **AND**

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. **One** of the following:
   a. If less than 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist, pediatric cardiologist, or heart and lung transplant specialist skilled in treating pulmonary hypertension
   b. If greater than or equal to 18 years of age, **one** of the following:
      a. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited center
      b. If unable to access a Pulmonary Hypertension Association-accredited center, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with an appropriate specialist (i.e., pulmonologist, cardiologist, or rheumatologist) skilled in treating pulmonary hypertension;

   **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

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5. For a diagnosis of PAH (WHO Group 1), all of the following:

   a. Has chart documentation of right heart catherization indicating all of the following hemodynamic values:
      
      a. A mean pulmonary arterial pressure greater than 20 mmHg,
      b. A pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 15 mmHg,
      c. A pulmonary vascular resistance greater than or equal to 3 Wood units,

   b. For a beneficiary with idiopathic PAH, both of the following:
      
      i. One of the following:
         
         a) Has a H₂FPEF score less than 2
         b) Has a left atrial volume index less than 35 mL/m²
         c) Has a negative provocative test in a heart catheterization lab (fluid challenge with pulmonary capillary wedge pressure, left atrial pressure, or left ventricular end-diastolic pressure less than or equal to 17 mmHg)

      ii. One of the following:
       
       a) Has chart documentation of acute vasoreactivity testing
       b) Has a contraindication to vasoreactivity testing or is at increased risk of adverse events during acute vasoreactivity testing (e.g., high risk stratification based on current risk calculator assessment (e.g., REVEAL 2.0), low systemic blood pressure, low cardiac index, or pulmonary veno-occlusive disease),
      
      c. For a beneficiary with idiopathic PAH that demonstrates acute vasoreactivity,¹ has a documented history of therapeutic failure, contraindication, or intolerance of calcium channel blockers (i.e., amlodipine, nifedipine, or diltiazem);

   AND

6. For a diagnosis of chronic thromboembolic pulmonary hypertension (CTEPH), has chart documentation of right heart catherization indicating both of the following hemodynamic values:

   a. A mean pulmonary arterial pressure greater than 20 mmHg
   b. A pulmonary vascular resistance greater than or equal to 3 Wood units;

   AND

7. For a non-preferred Pulmonary Hypertension Agent, Oral and Inhaled, one of the following:

¹ A positive vasoreactivity test is defined by a decrease in the mean pulmonary artery pressure by at least 10 mmHg to reach an absolute value of 40 mmHg or less without a decrease in cardiac output.
a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Pulmonary Hypertension Agents, Oral and Inhaled approved or medically accepted for the beneficiary’s diagnosis or indication

b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Pulmonary Hypertension Agent, Oral and Inhaled (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

See the Preferred Drug List (PDL) for the list of preferred Pulmonary Hypertension Agents, Oral and Inhaled at: https://papdl.com/preferred-drug-list;

AND

8. If the prescription for a Pulmonary Hypertension Agent, Oral and Inhaled is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR PULMONARY HYPERTENSION AGENTS, ORAL AND INHALED: The determination of medical necessity of a request for renewal of a prior authorization for a Pulmonary Hypertension Agent, Oral and Inhaled that was previously approved will take into account whether the beneficiary:

1. Continues to benefit from the requested Pulmonary Hypertension Agent, Oral and Inhaled based on the prescriber’s assessment; AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. One of the following:

   a. If less than 18 years of age, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a pediatric pulmonologist, pediatric cardiologist, or heart and lung transplant specialist

   b. If greater than or equal to 18 years of age, one of the following:

      i. Is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with a practitioner at a Pulmonary Hypertension Association-accredited
ii. If unable to access a Pulmonary Hypertension Association-accredited center, is prescribed the Pulmonary Hypertension Agent, Oral and Inhaled by or in consultation with an appropriate specialist (i.e., pulmonologist, cardiologist, or rheumatologist);

AND

4. Does not have a contraindication to the prescribed medication; AND

5. If the prescription for a Pulmonary Hypertension Agent, Oral and Inhaled is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Pulmonary Hypertension Agent, Oral and Inhaled. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

6. FDA Drug Safety Communication: FDA recommends against use of Revatio in children with...
pulmonary hypertension; September 21, 2012.


17. Pulmonary Hypertension Association Consensus Statement; Revatio (sildenafil) for Pediatric Use: September 2012.


Requirements for Prior Authorization of Pancreatic Enzymes

A. Revisions to Prescriptions That Require Prior Authorization

All prescriptions for non-preferred Pancreatic Enzymes must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Pancreatic Enzymes at: https://papdl.com/preferred-drug-list.

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Pancreatic Enzyme, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has one of the following:

   a. A documented history of therapeutic failure, contraindication, or intolerance of the preferred Pancreatic Enzymes
   b. A current history (within the past 90 days) of being prescribed the same nonpreferred Pancreatic Enzyme.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a non-preferred Pancreatic Enzyme. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Penicillins

A. Prescriptions That Require Prior Authorization

All prescriptions for non-preferred Penicillins must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Penicillins at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Penicillin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. One of the following:

   a. Has a history of therapeutic failure, intolerance, or contraindication of the preferred Penicillins
   b. Has culture and sensitivity test results documenting that only non-preferred Penicillins will be effective.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Penicillin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Phosphate Binders

A. Prescriptions That Require Prior Authorization

Prescriptions for Phosphate Binders that meet any of the following conditions must be prior authorized:

1. A non-preferred Phosphate Binder. See the Preferred Drug List (PDL) for the list of preferred Phosphate Binders at: https://papdl.com/preferred-drug-list.

2. A Phosphate Binder with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Phosphate Binder, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Phosphate Binder, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Phosphate Binders AND

2. If a prescription for a Phosphate Binder is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines that are set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Phosphate Binder. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Pituitary Suppressive Agents, LHRH

A. Prescriptions That Require Prior Authorization

All prescriptions for Pituitary Suppressive Agents, LHRH must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Pituitary Suppressive Agent, LHRH, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Pituitary Suppressive Agent, LHRH for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Does not have a contraindication to the prescribed medication; **AND**

5. For a diagnosis of central precocious puberty, all of the following:
   a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a pediatric endocrinologist,
   b. Is \( \leq 11 \) years of age for females or \( \leq 12 \) years of age for males,
   c. Experienced onset of secondary sexual characteristics earlier than 8 years in females and 9 years in males;
      **AND**

6. For an adolescent with gender dysphoria, both of the following:
   a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a pediatric endocrinologist, adolescent medicine specialist, or medical provider with experience and/or training in transgender medicine
   b. Is prescribed the Pituitary Suppressive Agent, LHRH in a manner consistent with the current World Professional Association for Transgender Health standards of care for the health of transsexual, transgender, and gender nonconforming people;
      **AND**

7. For an adult with gender dysphoria, both of the following:
a. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with an endocrinologist or medical provider with experience and/or training in transgender medicine
b. Is prescribed the Pituitary Suppressive Agent, LHRH in a manner consistent with current medical literature;

AND

8. For a diagnosis of endometriosis, all of the following:

a. Has one of the following:

   i. A diagnosis of endometriosis confirmed by laparoscopy
   ii. A diagnosis of endometriosis supported by chart documentation of an adequate work-up that includes the clinical rationale for the diagnosis,

b. Has a history of all of the following:

   i. Therapeutic failure of or a contraindication or an intolerance to non-steroidal anti-inflammatory drugs
   ii. Therapeutic failure (based on a 3-month trial) of or a contraindication or an intolerance to oral contraceptives,

c. Is prescribed the Pituitary Suppressive Agent, LHRH by or in consultation with a gynecologist;

AND

9. For preservation of ovarian function, is receiving cancer treatment that is associated with premature ovarian failure (based on NCCN guidelines or peer-reviewed medical literature);

AND

10. For Oriahnn (elagolix, estradiol, norethindrone; elagolix) and Myfembree (relugolix/estradiol/norethindrone acetate) for the management of heavy menstrual bleeding associated with uterine leiomyomas (fibroids) in premenopausal women, has a history of therapeutic failure (based on a 3-month trial) of or a contraindication or an intolerance to contraceptives; AND

11. For an elagolix-containing agent or Myfembree (relugolix/estradiol/norethindrone acetate), if the beneficiary has a history of depression and/or suicidal thoughts or behaviors or is currently receiving treatment for depression and/or suicidal thoughts or behavior, has a behavioral health assessment prior to use; AND

12. For a non-preferred Pituitary Suppressive Agent, LHRH, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Pituitary Suppressive Agents,
LHRH approved or medically accepted for the beneficiary’s indication. See the Preferred Drug List for the list of preferred Pituitary Suppressive Agents, LHRH at: https://papdl.com/preferred-drug-list; AND

13. If a prescription for a Pituitary Suppressive Agent, LHRH is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Pituitary Suppressive Agent, LHRH. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Platelet Aggregation Inhibitors

A. Prescriptions That Require Prior Authorization

Prescriptions for Platelet Aggregation Inhibitors that meet any of the following conditions must be prior authorized:

1. A non-preferred Platelet Aggregation Inhibitor. See the Preferred Drug List (PDL) for the list of preferred Platelet Aggregation Inhibitors at: https://papdl.com/preferred-drug-list.

2. A Platelet Aggregation Inhibitor with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Platelet Aggregation Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Platelet Aggregation Inhibitor, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Platelet Aggregation Inhibitors approved or medically accepted for the beneficiary’s diagnosis **AND**

2. If a prescription for a Platelet Aggregation Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Platelet Aggregation Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References


Requirements for Prior Authorization of Potassium Removing Agents

A. Prescriptions That Require Prior Authorization

All prescriptions for Potassium Removing Agents must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Potassium Removing Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND
2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND
4. Is prescribed the Potassium Removing Agent by or in consultation with a cardiologist or nephrologist; AND
5. Has documentation of recent serum potassium levels consistent with a diagnosis of hyperkalemia; AND
6. Has documented therapeutic failure of all of the following:
   a. A low potassium diet,
   b. A loop or thiazide diuretic, if clinically appropriate,
   c. Discontinuation or dose reduction to the minimum effective dose of medications known to cause hyperkalemia;
   AND
7. For a non-preferred Potassium Removing Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred Potassium Removing Agents. See the Preferred Drug List (PDL) for the list of preferred Potassium Removing Agents at: https://papdl.com/preferred-drug-list; AND
8. If a prescription for a Potassium Removing Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacieservices/quantitylimitslist/index.htm.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be
FOR RENEWALS OF PRESCRIPTIONS FOR POTASSIUM REMOVING AGENTS: The determination of medical necessity of requests for prior authorization of renewals of prescriptions for Potassium Removing Agents that were previously approved will take into account whether the beneficiary:

1. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

2. Is prescribed the Potassium Removing Agent by or in consultation with a cardiologist or nephrologist; **AND**

3. Has documentation of recent serum potassium levels demonstrating a positive clinical response to therapy; **AND**

4. If a prescription for a Potassium Removing Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm](http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm).

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of the request for a prescription for a Potassium Removing Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. **Dose and Duration of Therapy**

Requests for prior authorization of Potassium Removing Agents will be approved as follows:

1. Initial requests for prior authorization of Potassium Removing Agents will be approved for up to 3 months.

2. Renewals of requests for prior authorization of Potassium Removing Agents will be approved for up to 12 months.
E. References

Requirements for Prior Authorization of Prenatal Vitamins

A. **Revisions to Prescriptions That Require Prior Authorization**

Prescriptions for non-preferred Prenatal Vitamins must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Prenatal Vitamins at: https://papdl.com/preferred-drug-list.

B. **Revisions to Review of Documentation for Medical Necessity**

In evaluating a request for prior authorization of a prescription for a non-preferred Prenatal Vitamin, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Prenatal Vitamins.

   **NOTE:** If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Revisions to Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Prenatal Vitamin. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Progestational Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Progestational Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Progestational Agent. See the Preferred Drug List (PDL) for the list of preferred Progestational Agents at: https://papdl.com/preferred-drug-list.

2. A Progestational Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Progestational Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Progestational Agent, one of the following:
   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Progestational Agents approved or medically accepted for the beneficiary’s indication
   b. For an intravaginal Progestational Agent, is prescribed the intravaginal Progestational Agent for treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration-approved package labeling OR a medically accepted indication, excluding use to promote fertility,

   AND

2. If a prescription for a Progestational Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Progestational Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred
to a physician reviewer for a medical necessity determination. Such a request for prior
authorization will be approved when, in the professional judgment of the physician reviewer,
the services are medically necessary to meet the medical needs of the beneficiary.

D. References

1. U.S. Food & Drug Administration. Makena (hydroxyprogesterone caproate injection)
Information. Postmarket Drug Safety Information for Patients and Providers. April 6,
providers/makena-hydroxyprogesterone-caproate-injection-information.
Requirements for Prior Authorization of Proton Pump Inhibitors (PPIs)

A. Revisions to Prescriptions That Require Prior Authorization

Prescriptions for PPIs that meet any of the following conditions must be prior authorized:

1. A non-preferred PPI. See the Preferred Drug List (PDL) for the list of preferred PPIs at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list).

2. A PPI with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm](http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm).

3. A PPI for a child under six (6) years of age when a PPI has been prescribed for a total of four (4) months in the preceding 180-day period.

4. An over-the-counter (OTC) PPI for a dual-eligible beneficiary, regardless of the quantity prescribed.

5. A PPI when there is a record of a recent paid claim for another drug within the same therapeutic class of drugs in Point-of-Sale On-Line Claims Adjudication System (therapeutic duplication).

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a PPI, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Proton Pump Inhibitor, has a history of therapeutic failure, contraindication, or intolerance to the preferred PPIs; AND

2. For a child under six (6) years of age when a PPI has been prescribed for a total of four (4) months or more in the preceding 180-day period, at least one of the following:

   a. Has a chronic primary disease such as cystic fibrosis, cerebral palsy, Down’s Syndrome/mental retardation, or repaired esophageal atresia,
   b. Has documentation of a comprehensive evaluation and appropriate diagnostic testing confirming a diagnosis that requires chronic therapy,
   c. Is being prescribed the medication by or in consultation with a gastroenterologist;

   AND
3. For an OTC PPI for a dual-eligible beneficiary, both of the following:

   a. Is not being prescribed the OTC PPI as part of a Medicare Part D plan utilization management program, including a step-therapy or prior authorization program
   b. Has a history of therapeutic failure, contraindication, or intolerance to the PPIs on the beneficiary’s Medicare Part D plan formulary;

   AND

4. For therapeutic duplication, one of the following:

   a. Is being titrated to or tapered from a drug in the same class
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed literature or national treatment guidelines;

   AND

5. If a prescription for a PPI is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a PPI. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the PROTON PUMP INHIBITORS guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Prescriptions for Drugs that Exceed the Established Quantity Limits/Daily Dose Limits

A. Prescriptions That Require Prior Authorization

Prescriptions for drugs included in the Quantity Limits/Daily Dose Limits List that exceed the established quantity limits/daily dose limits must be prior authorized. For the list of drugs with quantity limits/daily dose limits and the established quantity limits, see:
https://www.dhs.pa.gov/providers/Pharmacy-Services/Documents/Quantity%20Limits/QL%20List-Current%20as%20of%2010-01-19.pdf

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription with a quantity that exceeds the established quantity limit/daily dose limit, the determination of whether the requested prescription is medically necessary will take into account the following:

1. Whether the recipient requires a dose that includes half tablets

   OR

2. Whether the recipient’s dose is being titrated by the prescriber (3 month limit)

   OR

3. Whether the recipient has a history of intolerance of a drug administered as a single daily dose

   OR

4. Whether the quantity prescribed is consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed literature or national treatment guidelines that corroborate use of the quantity of medication being prescribed

   OR

5. Whether the recipient does not meet the clinical review guidelines listed above, but, in the professional judgment of the
physician reviewer, the services are medically necessary to meet the medical needs of the recipient.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical review criteria in Section B to assess the medical necessity of the request for a prescription that exceeds the established quantity/daily dose limits. If any of the applicable guidelines in Section B are met, the reviewer will prior authorize the prescription. If none of the applicable guidelines are met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such requests for service may be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the recipient.
I. Requirements for Prior Authorization of Sedative Hypnotics

A. Prescriptions That Require Prior Authorization

Prescriptions for Sedative Hypnotics that meet any of the following conditions must be prior authorized:

1. A non-preferred Sedative Hypnotic. See the Preferred Drug List (PDL) for the list of preferred Sedative Hypnotics at: https://papdl.com/preferred-drug-list.

2. A Sedative Hypnotic benzodiazepine when prescribed for a beneficiary under 21 years of age.

3. A Sedative Hypnotic benzodiazepine when there is a record of a recent paid claim for another benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication).

4. A Sedative Hypnotic benzodiazepine when there is a record of 2 or more paid claims for any benzodiazepine (excluding clobazam and benzodiazepines indicated for the acute treatment of increased seizure activity [e.g., rectal and nasal formulations]) in the Point-of-Sale Online Claims Adjudication System within the past 30 days.

5. A Sedative Hypnotic that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance) when a beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

6. A Sedative Hypnotic with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Sedative Hypnotic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a Sedative Hypnotic benzodiazepine for a beneficiary under 21 years of age, one of the following:
   a. Has a diagnosis of one of the following:
      i. Seizure disorder,
      ii. Chemotherapy induced nausea and vomiting,
      iii. Cerebral palsy,
      iv. Spastic disorder,
      v. Dystonia,
      vi. Catatonia
b. Is receiving palliative care;

**AND**

2. For a diagnosis of non-24-hour sleep-wake disorder, **one** of the following:

   a. Has a documented history of therapeutic failure of a 6-month trial of melatonin
   b. Has documented contraindication or intolerance to melatonin;

**AND**

3. For a non-preferred Sedative Hypnotic, **both** of the following:

   a. Is prescribed the Sedative Hypnotic for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication
   b. Has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Sedative Hypnotics approved or medically accepted for the beneficiary’s diagnosis or indication;

**AND**

4. For a non-preferred controlled-release Sedative Hypnotic, has a documented history of therapeutic failure of the same regular-release Sedative Hypnotic; **AND**

5. For therapeutic duplication of a benzodiazepine, **one** of the following:

   a. Is being titrated to or tapered from another benzodiazepine
   b. Has a medical reason for concomitant use of the requested medications that is supported by peer-reviewed medical literature or national treatment guidelines;

**AND**

6. When there is a record of 2 or more paid claims for any benzodiazepine, **both** of the following:

   a. The multiple prescriptions are consistent with medically accepted prescribing practices and standards of care, including support from peer-reviewed medical literature or national treatment guidelines
   b. The multiple prescriptions are written by the same prescriber or, if written by different prescribers, all prescribers are aware of the other prescription(s);

**AND**

7. For a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, **both** of the following:

   a. Is prescribed the buprenorphine agent and the Sedative Hypnotic controlled substance by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
b. Has an acute need for therapy with the Sedative Hypnotic controlled substance;

**AND**

8. For a Sedative Hypnotic that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance), one of the following:
   
a. Meets the guidelines in B.1.
   b. Has documentation that the prescriber or the prescriber’s delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary’s controlled substance prescription history;

**AND**

9. If a prescription for a Sedative Hypnotic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR SEDATIVE HYPNOTICS: The determination of medical necessity of a request for renewal of a prior authorization for a Sedative Hypnotic that was previously approved will take into account whether the beneficiary:

1. For a Sedative Hypnotic benzodiazepine for a beneficiary under 21 years of age, one of the following:
   
a. Has a diagnosis of one of the following:
      
      i. Seizure disorder,
      ii. Chemotherapy induced nausea and vomiting,
      iii. Cerebral palsy,
      iv. Spastic disorder,
      v. Dystonia,
      vi. Catatonia
   
b. Is receiving palliative care;

**AND**

2. Has documentation of tolerability and a positive clinical response to the medication; **AND**

3. For a Sedative Hypnotic that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance), one of the following:
   
a. Meets the guidelines in RENEWAL B.1.
b. Has documentation that the prescriber or the prescriber’s delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program (PDMP) for the beneficiary’s controlled substance prescription history;

**AND**

4. If the prescription for a Sedative Hypnotic is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Sedative Hypnotic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Skeletal Muscle Relaxants

A. Prescriptions That Require Prior Authorization

Prescriptions for Skeletal Muscle Relaxants that meet any of the following conditions must be prior authorized:

1. A non-preferred Skeletal Muscle Relaxant. See the Preferred Drug List (PDL) for the list of preferred Skeletal Muscle Relaxants at: https://papdl.com/preferred-drug-list.

2. A Skeletal Muscle Relaxant with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

3. A Skeletal Muscle Relaxant that is subject to the U.S. Drug Enforcement Agency Controlled Substances Act (i.e., controlled substance) when the beneficiary has a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Skeletal Muscle Relaxant, the determination of whether the requested prescription is medically necessary will take into account the whether the beneficiary:

1. For a non-preferred Skeletal Muscle Relaxant, has a history of therapeutic failure, contraindication, or intolerance to the preferred Skeletal Muscle Relaxants approved or medically accepted for the beneficiary’s diagnosis; AND

2. For a Skeletal Muscle Relaxant that is a controlled substance for a beneficiary with a concurrent prescription for a buprenorphine agent indicated for the treatment of opioid use disorder, both of the following:

   a. Is prescribed the buprenorphine agent and the Skeletal Muscle Relaxant by the same prescriber or, if prescribed by different prescribers, all prescribers are aware of the other prescription(s)
   
   b. Has an acute need for therapy with the Skeletal Muscle Relaxant;

   AND

3. For a Skeletal Muscle Relaxant that is a controlled substance, has documentation that the prescriber or the prescriber’s delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program for the beneficiary’s controlled substance prescription history; AND

4. If a prescription for a Skeletal Muscle Relaxant is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

January 3, 2022
NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Skeletal Muscle Relaxant. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Sickle Cell Anemia Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Sickle Cell Anemia Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Sickle Cell Anemia Agent. See the Preferred Drug List (PDL) for the list of preferred Sickle Cell Anemia Agents at: https://papdl.com/preferred-drug-list.

2. A Sickle Cell Anemia Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Sickle Cell Anemia Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Sickle Cell Anemia Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed the Sickle Cell Anemia Agent by or in consultation with a hematologist/oncologist or sickle cell disease specialist; AND

5. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); AND
6. Has a history of therapeutic failure, contraindication, or intolerance to maximum tolerated doses of hydroxyurea for at least 6 months; AND

7. If a prescription for a Sickle Cell Anemia Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR SICKLE CELL ANEMIA AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Sickle Cell Anemia Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication; AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed the Sickle Cell Anemia Agent by or in consultation with a hematologist/oncologist or sickle cell disease specialist; AND

4. Had all potential drug interactions addressed by the prescriber (such as discontinuation of the interacting drug, dose reduction of the interacting drug, or counseling of the beneficiary of the risks associated with the use of both medications when they interact); AND

5. If a prescription for a Sickle Cell Anemia Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Sickle Cell Anemia Agent. If the guidelines in Section B. are met, the reviewer will
prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

I. Requirements for Prior Authorization of Smoking Cessation Products

A. Prescriptions That Require Prior Authorization

Prescriptions for Smoking Cessation Products that meet any of the following conditions must be prior authorized:

1. A non-preferred Smoking Cessation Product. See the Preferred Drug List (PDL) for the list of preferred Smoking Cessation Products at: https://papdl.com/preferred-drug-list.

2. A Smoking Cessation Product with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Smoking Cessation Product, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Smoking Cessation product, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Smoking Cessation Products AND

2. If a prescription for a Smoking Cessation Product is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Smoking Cessation Product. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Steroids, Topical

A. **Prescriptions That Require Prior Authorization**

   All prescriptions for a non-preferred Steroid, Topical must be prior authorized.

   See the Preferred Drug List (PDL) for the list of preferred Steroids, Topical at: https://papdl.com/preferred-drug-list.

B. **Revisions to Review of Documentation for Medical Necessity**

   In evaluating a request for prior authorization of a prescription for a non-preferred Steroid, Topical, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

   1. Has a history of therapeutic failure, contraindication, or intolerance to the preferred Steroids, Topical of the same relative potency (i.e., low, medium, high, very high) and approved or medically accepted for the beneficiary’s diagnosis.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

   Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Steroid, Topical. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Stimulants and Related Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Stimulants and Related Agents that meet the following conditions must be prior authorized.

1. A non-preferred Stimulants and Related Agent. See the Preferred Drug List (PDL) for the list of preferred Stimulants and Related Agents at: https://papdl.com/preferred-drug-list.

2. A Stimulants and Related Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

3. A Stimulants and Related Agent for a beneficiary under 4 years of age.

4. A prescription for an analeptic Stimulants and Related Agent (e.g., armodafinil, modafinil, etc.).

5. A Stimulants and Related Agent when there is a record of a recent paid claim for another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) in the Point-of-Sale Online Claims Adjudication System (therapeutic duplication). EXCEPTIONS: Intuniv (guanfacine ER), Kapvay (clonidine ER), an analeptic Stimulants and Related Agent.

6. A Stimulants and Related Agent when prescribed for a beneficiary 18 years of age or older. EXCEPTION: an analeptic Stimulants and Related Agent.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Stimulants and Related Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a request for Evekeo (amphetamine) for the treatment of obesity, see the prior authorization guidelines related to Obesity Treatment Agents; OR

2. For a non-preferred Stimulants and Related Agent, except an analeptic agent, one of the following:
   
   a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Stimulants and Related Agents approved or medically accepted for the beneficiary’s diagnosis
   
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Stimulants and Related Agent;

   AND
3. For an analeptic Stimulants and Related Agent, all of the following:

   a. Is not receiving concurrent treatment with sedative hypnotics,

   b. Is prescribed the analeptic Stimulants and Related Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,

   c. For the treatment of narcolepsy and shift work sleep disorder, has a diagnosis confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders),

   d. For the treatment of obstructive sleep apnea/hypopnea syndrome (OSAHS), has both of the following:

      i. A diagnosis of OSAHS confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders)
      
      ii. A history of therapeutic failure of continuous positive airway pressure (CPAP) to resolve excessive daytime sleepiness (documented by either Epworth Sleepiness Scale greater than 10 or multiple sleep latency test (MSLT) less than 8 minutes) with documented compliance to CPAP treatment or, if the beneficiary has a medical reason CPAP cannot be used, therapeutic failure of an oral appliance for OSAHS,

   e. For the treatment of multiple sclerosis-related fatigue, is receiving treatment for multiple sclerosis or, if not being treated, the medical record documents the rationale for the beneficiary not being treated,

   f. For a non-preferred analeptic Stimulants and Related Agent, has a history of therapeutic failure, contraindication, or intolerance of the preferred analeptic Stimulants and Related Agents approved or medically accepted for the beneficiary’s diagnosis;

   AND

4. For a beneficiary under 4 years of age, all of the following:

   a. Is prescribed the Stimulants and Related Agent for an indication that is included in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication,

   b. Is being prescribed the medication by or in consultation with one of the following:

      i. Pediatric neurologist,
      
      ii. Child and adolescent psychiatrist,
      
      iii. Child development pediatrician,
c. Has chart-documented evidence of a comprehensive evaluation by or in consultation with a specialist listed above;

AND

5. For a beneficiary 18 years of age or older, all of the following:

a. Is prescribed the Stimulants and Related Agent for an indication that is included in the FDA-approved package labeling OR a medically accepted indication,

b. For the treatment of attention deficit hyperactivity disorder (ADHD), has a diagnosis of ADHD as documented by a history consistent with the current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria,

c. For the treatment of moderate to severe binge eating disorder, all of the following:

   i. Has a diagnosis documented by a history that is consistent with the current DSM criteria,
   ii. In the absence of a diagnosis of ADHD or attention deficit disorder (ADD), has a documented history of therapeutic failure, contraindication, or intolerance to selective serotonin reuptake inhibitors or topiramate,
   iii. Has documentation of a referral for cognitive behavioral therapy or other psychotherapy,

d. For the treatment of narcolepsy, has the diagnosis confirmed according to the most recent consensus treatment guidelines (e.g., American Academy of Sleep Medicine International Classification of Sleep Disorders),

e. For a Stimulant Agent, all of the following:

   i. Was assessed for potential risk of misuse, abuse, or addiction based on family and social history obtained by the prescribing provider,
   ii. Has documentation that the beneficiary has been educated on the potential adverse effects of stimulants, including the risk for misuse, abuse, and addiction,
   iii. Has documentation that the prescriber or prescriber’s delegate conducted a search of the Pennsylvania Prescription Drug Monitoring Program for the beneficiary’s controlled substance prescription history,

f. For a Stimulant Agent for a beneficiary with a history of comorbid substance dependency, abuse, or diversion, has results of a recent urine drug screen testing for licit and illicit drugs with the potential for abuse (including specific testing for oxycodone, fentanyl, and tramadol) that is consistent with prescribed controlled substances;

AND

6. For therapeutic duplication, one of the following:
a. Is being transitioned to another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) with the intent of discontinuing one of the medications
b. Supporting peer-reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested;

AND

7. If a prescription for a Stimulants and Related Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR A STIMULANTS AND RELATED AGENT: The determination of medical necessity of a request for renewal of a prior authorization for a Stimulants and Related Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation of tolerability and a positive clinical response to the medication; AND

2. For therapeutic duplication, one of the following:
   a. Is being transitioned to another Stimulants and Related Agent with the same duration of action (i.e., short-acting or long-acting) with the intent of discontinuing one of the medications
   b. Supporting peer-reviewed literature or national treatment guidelines corroborate concomitant use of the medications being requested;

AND

3. If a prescription for a Stimulants and Related Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Stimulants and Related Agent. If the guidelines in Section B. are met, the reviewer will prior
authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

All requests for prior authorization of a prescription for a Stimulants and Related Agent for a Medical Assistance beneficiary under 4 years of age will be automatically forwarded to a physician reviewer (a psychiatrist) for a medical necessity determination. The physician reviewer (a psychiatrist) will consider the guidelines in Section B. above and will approve the request when, in the professional judgment of the physician reviewer (a psychiatrist), the services are medically necessary to meet the medical needs of the beneficiary.

D. References:

8. Searight HR, et.al. Adult ADHD: evaluation and treatment in family medicine, American Family Physician, 2000 Nov 1; 62(9).
Requirements for Prior Authorization of Tetracyclines

A. Revisions to Prescriptions That Require Prior Authorization

**Prescriptions for Tetracyclines that meet any of the following conditions** must be prior authorized:

1. A non-preferred Tetracycline. See the Preferred Drug List (PDL) for the list of preferred Tetracyclines at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list).

2. **A Tetracycline with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at:**

B. Revisions to Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Tetracycline, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. **For a non-preferred Tetracycline, one of the following:**
   a. Has a history of therapeutic failure, intolerance, or contraindication to the preferred Tetracyclines approved or medically accepted for the beneficiary’s diagnosis.
   b. Has culture and sensitivity test results documenting that only non-preferred Tetracyclines will be effective; **AND**

2. **If a prescription for a Tetracycline is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.**

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Revisions to Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Tetracycline. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Thalidomide and Derivatives

A. Prescriptions That Require Prior Authorization

All prescriptions for Thalidomide and Derivatives must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Thalidomide and Derivative, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Thalidomide and Derivative by or in consultation with an appropriate specialist (i.e., hematologist/oncologist); AND

2. Is prescribed the Thalidomide and Derivative for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. For a non-preferred Thalidomide and Derivative, one of the following:

   a. Has a documented history of therapeutic failure, contraindication, or intolerance to the preferred Thalidomide and Derivatives approved or medically accepted for the beneficiary's diagnosis
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Thalidomide and Derivative

See the Preferred Drug List (PDL) for the list of preferred Thalidomide and Derivatives at: https://papdl.com/preferred-drug-list;

AND

5. If a prescription for a Thalidomide and Derivative is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.
FOR RENEWALS OF PRESCRIPTIONS FOR THALIDOMIDE AND DERIVATIVES: The determination of medical necessity of a request for prior authorization for a Thalidomide and Derivative that was previously approved will take into account whether the beneficiary:

1. Has documentation from the prescriber of tolerability and a positive clinical response to the medication; **AND**

2. Is prescribed the Thalidomide and Derivative by or in consultation with an appropriate specialist (i.e., hematologist/oncologist); **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. If a prescription for a Thalidomide and Derivative is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm](http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Thalidomide and Derivative. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Thrombopoietics

A. Prescriptions that Require Prior Authorization

All prescriptions for Thrombopoietics must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Thrombopoietic, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Thrombopoietic by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, gastroenterologist, hepatologist, etc.); AND

2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. One of the following:
   a. For a request for treatment of thrombocytopenia prior to a procedure, both of the following:
      i. Has a documented pretreatment platelet count < 50 x 10^9/L
      ii. Will begin treatment with the requested Thrombopoietic prior to the scheduled procedure in accordance with FDA-approved package labeling
   b. For a request for treatment of other indications, has a documented pretreatment platelet count < 30 x 10^9/L; AND

5. Has documentation of baseline lab results and monitoring as recommended in the FDA-approved package labeling; AND

6. For a request for a non-preferred Thrombopoietic, has documented therapeutic failure, contraindication, or intolerance to the preferred Thrombopoietics approved for the beneficiary’s indication. See the Preferred Drug List (PDL) for the list of preferred Thrombopoietics at: https://papdl.com/preferred-drug-list; AND

7. If a prescription for a Thrombopoietic is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR THROMBOPOIETICS: The determination of medical necessity of a request for renewal of a prior authorization for a Thrombopoietic prescribed for an indication other than thrombocytopenia in a beneficiary scheduled to undergo a procedure that was previously approved will take into account whether the beneficiary:

1. Is prescribed the Thrombopoietic by or in consultation with an appropriate specialist (i.e., hematologist/oncologist, gastroenterologist, hepatologist, etc.); **AND**

2. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. **One** of the following:
   a. Has a documented increased platelet count sufficient to avoid bleeding that requires medical attention
   b. For treatment of severe aplastic anemia, has documentation of a positive clinical response;
   **AND**

4. Has documentation of repeat lab results and monitoring as recommended in the FDA-approved package labeling; **AND**

5. For renewal requests for Tavalisse (fostamatinib), does not have ≥ grade 3 diarrhea or has a documented plan to manage the diarrhea that is consistent with FDA-approved package labeling; **AND**

6. If a prescription for a Thrombopoietic is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [http://www.dhs.pa.gov/provider/pharmacieservices/quantitylimitslist/index.htm](http://www.dhs.pa.gov/provider/pharmacieservices/quantitylimitslist/index.htm).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Thrombopoietic. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
D. **Dose and Duration of Therapy**

1. Initial and renewal requests for prior authorization of Thrombopoietics will be approved for up to 6 months unless otherwise indicated below.

2. Initial requests for prior authorization of Nplate (romiplostim) for the treatment of ITP will be approved for up to 2 months of therapy.

3. Initial requests for prior authorization of Promacta (eltrombopag) for the treatment of ITP will be approved for up to 2 months of therapy.

4. Initial requests for prior authorization of Promacta (eltrombopag) for the treatment of refractory severe aplastic anemia will be approved for up to 5 months of therapy.

5. Requests for prior authorization of Promacta (eltrombopag) for the primary treatment of aplastic anemia will be limited to one 6-month course of treatment.

6. Initial requests for prior authorization of Tavalisse (fostamatinib) for the treatment of ITP will be approved for up to 4 months of therapy.

7. Requests for prior authorization of Doptelet (avatrombopag) for the treatment of thrombocytopenia prior to a procedure will be approved for 5 days.

8. Requests for prior authorization of Mulpleta (lusutrombopag) for the treatment of thrombocytopenia prior to a procedure will be approved for 7 days.

   **NOTE:** Requests for additional courses of therapy of Doptelet (avatrombopag) or Mulpleta (lusutrombopag) for the treatment of thrombocytopenia prior to a procedure will be considered to be an initial request.

E. **References**


I. Requirements for Prior Authorization of Thyroid Hormones

A. Prescriptions That Require Prior Authorization

Prescriptions for Thyroid Hormones that meet any of the following conditions must be prior authorized:

1. A non-preferred Thyroid Hormone. See the Preferred Drug List (PDL) for the list of preferred Thyroid Hormones at: https://papdl.com/preferred-drug-list.

2. A Thyroid Hormone with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Thyroid Hormone, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Thyroid Hormone, has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Thyroid Hormones AND

2. If a prescription for a Thyroid Hormone is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Thyroid Hormone. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of Tysabri (natalizumab)

A. Prescriptions That Require Prior Authorization

All prescriptions for Tysabri (natalizumab) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Tysabri (natalizumab), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Tysabri (natalizumab) for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

4. Is prescribed Tysabri (natalizumab) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of Crohn’s disease); AND

5. Does not have a contraindication to Tysabri (natalizumab); AND

6. Is not receiving chronic immunosuppressant or immunomodulator therapy; AND

7. For treatment of Crohn’s disease, both of the following:

   a. One of the following:

      i. For a diagnosis of moderate to severe Crohn’s disease, one of the following:

         a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids

         b) One of the following:

            (i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines

            (ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines

   ii. Has a diagnosis of Crohn’s disease that is associated with one or more high-risk or

1 e.g., American College of Gastroenterology [ACG], American Gastroenterological Association [AGA], Canadian Association of Gastroenterology [CAG], European Crohn’s and Colitis Organization [ECCO]
poor prognostic feature(s),

iii. **Both** of the following:

   a) Has achieved remission with Tysabri (natalizumab)
   b) Will be using Tysabri (natalizumab) as maintenance therapy to maintain remission

b. **One** of the following:

   i. **All** of the following:

   a) **One** of the following:

      (i) Has a history of therapeutic failure of at least 1 tumor necrosis factor (TNF) inhibitor indicated or medically accepted for the treatment of Crohn’s disease
      (ii) Has a history of a contraindication or an intolerance to the TNF inhibitors indicated or medically accepted for the treatment of Crohn’s disease,

   b) Has a history of therapeutic failure of or a contraindication or an intolerance to ustekinumab,

   c) Has a history of therapeutic failure of or a contraindication or an intolerance to vedolizumab

   ii. Has a current history (within the past 90 days) of being prescribed Tysabri (natalizumab);

**AND**

8. If a prescription for Tysabri (natalizumab) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR TYSABRI (NATALIZUMAB): The determination of medical necessity of a request for renewal of a prior authorization for Tysabri (natalizumab) that was previously approved will take into account whether the beneficiary:

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2 Examples of high-risk or poor prognostic features in patients with Crohn’s disease include: initial diagnosis or clinical evidence supports the onset of symptoms at <30 years of age, extensive anatomic involvement, presence of fistula, perianal and/or severe rectal disease, large or deep mucosal lesions on endoscopy or imaging, prior surgical resection, stricturing and/or penetrating behavior, need for steroid therapy at initial diagnosis, extra-intestinal manifestations, and laboratory markers such as low hemoglobin, low albumin, high C-reactive protein, and high fecal calprotectin levels (AGA 2014; ECCO 2017; CAG 2019; AGA 2021).
1. For a diagnosis of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course; **AND**

2. For a diagnosis of Crohn’s disease, **both** of the following:
   
a. **One** of the following:
   
   i. Has documentation of therapeutic benefit within 3 months of starting therapy
   ii. Was able to discontinue concomitant corticosteroid use within 6 months of starting therapy
   
   b. Did not require additional steroid use for disease control for more than 3 months in a calendar year;

   **AND**

3. If a prescription for Tysabri (natalizumab) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. See Quantity Limits List: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. **Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Tysabri (natalizumab). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the service is medically necessary to meet the medical needs of the beneficiary.

D. **Dose and Duration of Therapy**

Requests for prior authorization of Tysabri (natalizumab) will be approved as follows:

1. For a diagnosis of multiple sclerosis:
   
a. Initial requests will be approved for up to 6 months.
   b. Renewal requests will be approved for up to 12 months.

2. For a diagnosis of Crohn’s disease:
   
a. If the beneficiary is not taking chronic oral corticosteroids when starting Tysabri (natalizumab), initial requests will be approved for up to 3 months.
b. If the beneficiary is taking chronic oral corticosteroids when starting Tysabri (natalizumab), initial requests will be approved for up to 6 months to allow tapering of the corticosteroids.

c. Renewal requests will be approved for up to 12 months.

E. References

I. Requirements for Prior Authorization of Ulcerative Colitis Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Ulcerative Colitis Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Ulcerative Colitis Agent. See the Preferred Drug List (PDL) for the list of preferred Ulcerative Colitis Agents at: https://papdl.com/preferred-drug-list.

2. A prescription for Zeposia (ozanimod).

3. An Ulcerative Colitis Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for an Ulcerative Colitis Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For Zeposia (ozanimod), see the provider handbook pages in the SECTION II chapter related to Zeposia (ozanimod); OR

2. For a non-preferred Ulcerative Colitis Agent, one of the following:
   a. Has a history of therapeutic failure, contraindication, or intolerance of the preferred Ulcerative Colitis Agents
   b. Has a current history (within the past 90 days) of being prescribed the same non-preferred Ulcerative Colitis Agent (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred);

   AND

3. If a prescription for an Ulcerative Colitis Agent is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

   NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for an
Ulcerative Colitis Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Urea Cycle Disorder Agents

A. Prescriptions That Require Prior Authorization

Prescriptions for Urea Cycle Disorder Agents that meet any of the following conditions must be prior authorized:

1. A non-preferred Urea Cycle Disorder Agent. See the Preferred Drug List (PDL) for the list of preferred Urea Cycle Disorder Agents at: https://papdl.com/preferred-drug-list.

2. A Urea Cycle Disorder Agent with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Urea Cycle Disorder Agent, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the Urea Cycle Disorder Agent by or in consultation with a physician who specializes in treating metabolic disorders; AND

2. Is being treated for a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; AND

3. Has chart documentation supporting the diagnosis (e.g., ammonia levels, genetic testing, enzyme assays, plasma amino acid/urine orotic acid analyses, progress notes); AND

4. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

5. For a non-preferred Urea Cycle Disorder Agent, has a documented history of therapeutic failure, contraindication, or intolerance to the preferred Urea Cycle Disorder Agent; AND

6. If a prescription for a Urea Cycle Disorder Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRESCRIPTIONS FOR UREA CYCLE DISORDER AGENTS: The determination of medical necessity of a request for renewal of a prior authorization for a Urea Cycle Disorder Agent that was previously approved will take into account whether the beneficiary:

1. Has documentation from the prescribing provider that the beneficiary had a positive clinical response to therapy; AND
2. Is prescribed the Urea Cycle Disorder Agent by or in consultation with a physician who specializes in treating metabolic disorders; **AND**

3. Is prescribed a dose and duration of therapy that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. If a prescription for a Urea Cycle Disorder Agent is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

**C. Clinical Review Process**

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Urea Cycle Disorder Agent. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

**D. References**

4. Ravicti Prescribing Information. Lake Forest, IL. Horizon Therapeutics, LLC.
Requirements for Prior Authorization of Urinary Anti-Infectives

A. Prescriptions That Require Prior Authorization

Prescriptions for Urinary Anti-Infectives that meet any of the following conditions must be prior authorized:

1. A non-preferred Urinary Anti-Infective. See the Preferred Drug List (PDL) for the list of preferred Urinary Anti-Infectives at: https://papdl.com/preferred-drug-list.

2. A Urinary Anti-Infective with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

EXEMPTION FROM PRIOR AUTHORIZATION: Nitrofurantoin suspension is exempt from prior authorization when prescribed for a child under 9 years of age.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Urinary Anti-Infective, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Urinary Anti-Infective, has a history of therapeutic failure, contraindication, or intolerance of the preferred Urinary Anti-Infectives approved or medically accepted for the beneficiary’s diagnosis; **AND**

2. If a prescription for a Urinary Anti-Infective is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Urinary Anti-Infective. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Vaginal Anti-Infectives

A. Prescriptions That Require Prior Authorization

All prescriptions for a non-preferred Vaginal Anti-Infective must be prior authorized.

See the Preferred Drug List (PDL) for the list of preferred Vaginal Anti-Infectives at: https://papdl.com/preferred-drug-list.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a non-preferred Vaginal Anti-Infective, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Has a documented history of therapeutic failure, contraindication, or intolerance of the preferred Vaginal Anti-Infectives approved or medically accepted for the beneficiary’s diagnosis.

   NOTE: If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Vaginal Anti-Infective. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
Requirements for Prior Authorization of Vitamin D Analogs

A. Prescriptions That Require Prior Authorization

Prescriptions for a Vitamin D Analog that meet any of the following conditions must be prior authorized:

1. A non-preferred Vitamin D Analog. See the Preferred Drug List (PDL) for the list of preferred Vitamin D Analogs at: https://papdl.com/preferred-drug-list.

2. A Vitamin D Analog with a prescribed quantity that exceeds the quantity limit. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: http://www.dhs.pa.gov/provider/pharmacyservices/quantitylimitslist/index.htm.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a Vitamin D Analog, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. For a non-preferred Vitamin D Analog, has a history of therapeutic failure, intolerance, or contraindication of the preferred Vitamin D Analogs approved or medically accepted for the beneficiary’s diagnosis; **AND**

2. If a prescription for a Vitamin D Analog is in a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter.

**NOTE:** If the beneficiary does not meet the clinical review guidelines above but, in the professional judgement of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a Vitamin D Analog. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.
I. Requirements for Prior Authorization of VMAT2 Inhibitors

A. Prescriptions That Require Prior Authorization

All prescriptions for VMAT2 Inhibitors must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for a VMAT2 Inhibitor, the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed the VMAT2 Inhibitor for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling OR a medically accepted indication; **AND**

2. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

3. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

4. Is being prescribed the VMAT2 Inhibitor by or in consultation with a neurologist or a psychiatrist; **AND**

5. Does not have a contraindication to the prescribed medication; **AND**

6. **One** of the following:

   a. For a beneficiary with a history of a prior suicide attempt, bipolar disorder, or major depressive disorder, was evaluated within the previous 6 months and treated by a psychiatrist
   b. For all others, had a mental health evaluation performed;

   **AND**

7. If being treated for a diagnosis of tardive dyskinesia, **all** of the following:

   a. Was assessed for and determined to have no other causes of involuntary movement,
   b. Was evaluated for appropriateness of dose decrease of dopamine receptor blocking agents,
   c. Has documentation of tardive dyskinesia severity using a validated scale or assessment of impact on daily function;

   **AND**

8. For a non-preferred VMAT2 Inhibitor, has a documented therapeutic failure or intolerance to the preferred VMAT2 Inhibitors approved or medically accepted for the beneficiary’s
See the Preferred Drug List (PDL) for the list of preferred VMAT2 Inhibitors at: https://papdl.com/preferred-drug-list; AND

9. If a prescription for a VMAT2 inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR VMAT2 INHIBITORS: The determination of medical necessity of a request for renewal of a prior authorization for a VMAT2 Inhibitor that was previously approved will take into account whether the beneficiary:

1. One of the following:
   a. For a diagnosis of chorea, experienced a clinical benefit from the prescribed VMAT2 inhibitor based on the prescriber’s clinical judgment
   b. For a diagnosis of tardive dyskinesia, experienced an improvement in tardive dyskinesia severity documented by a validated scale or improvement in daily function;

   AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Is being prescribed the VMAT2 Inhibitor by or in consultation with a neurologist or a psychiatrist; AND

4. Does not have a contraindication to the prescribed medication; AND

5. Was re-evaluated and treated for new onset or worsening symptoms of depression and determined to continue to be a candidate for treatment with the prescribed VMAT2 Inhibitor; AND

6. If a prescription for a VMAT2 Inhibitor is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to
meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for a VMAT2 Inhibitor. If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References


January 3, 2022
I. Requirements for Prior Authorization of Zeposia (ozanimod)

A. Prescriptions That Require Prior Authorization

All prescriptions for Zeposia (ozanimod) must be prior authorized.

B. Review of Documentation for Medical Necessity

In evaluating a request for prior authorization of a prescription for Zeposia (ozanimod), the determination of whether the requested prescription is medically necessary will take into account whether the beneficiary:

1. Is prescribed Zeposia (ozanimod) for the treatment of a diagnosis that is indicated in the U.S. Food and Drug Administration (FDA)-approved package labeling or a medically accepted indication; **AND**

2. Is prescribed Zeposia (ozanimod) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of ulcerative colitis); **AND**

3. Does not have a contraindication to Zeposia (ozanimod); **AND**

4. Is prescribed a dose that is consistent with the FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; **AND**

5. Is age-appropriate according to FDA-approved package labeling, nationally recognized compendia, or peer-reviewed literature; **AND**

6. For treatment of multiple sclerosis, **one** of the following:
   
   a. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Multiple Sclerosis Agents approved for the beneficiary’s diagnosis
   b. Has a current history (within the past 90 days) of being prescribed Zeposia (ozanimod) (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

   See the Preferred Drug List (PDL) for the list of preferred Multiple Sclerosis Agents at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list);

   **AND**

7. For treatment of ulcerative colitis (UC), **both** of the following:

   a. **Both** of the following:

      i. Has **one** of the following diagnoses:
a) Mild UC that is associated with multiple poor prognostic factors
b) Moderate to severe UC

ii. **One** of the following:

a) Failed to achieve remission with or has a contraindication or an intolerance to an induction course of corticosteroids,

b) **One** of the following:

(i) Failed to maintain remission with an immunomodulator in accordance with current consensus guidelines (e.g., American College of Gastroenterology, American Gastroenterological Association, European Crohn’s and Colitis Organization, etc.)

(ii) Has a contraindication or an intolerance to immunomodulators in accordance with current consensus guidelines,

c) **Both** of the following:

(i) Has achieved remission with Zeposia (ozanimod)

(ii) Will be using Zeposia (ozanimod) as maintenance therapy to maintain remission

b. **One** of the following:

i. Has a history of therapeutic failure of or a contraindication or an intolerance to the preferred Cytokine and CAM Antagonists approved or medically accepted for treatment of ulcerative colitis

ii. Has a current history (within the past 90 days) of being prescribed Zeposia (ozanimod) (does not apply to non-preferred brands when the therapeutically equivalent generic is preferred or to non-preferred generics when the therapeutically equivalent brand is preferred)

See the Preferred Drug List (PDL) for the list of preferred Cytokine and CAM Antagonists at: [https://papdl.com/preferred-drug-list](https://papdl.com/preferred-drug-list);

AND

8. If a prescription for Zeposia (ozanimod) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: [https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx](https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx).

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically

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1 Poor prognostic factors include initial diagnosis or clinical evidence supports the onset of symptoms at <40 years of age, extensive colitis, severe endoscopic disease (presence of large and/or deep ulcers), hospitalization for colitis, elevated inflammatory markers, low serum albumin, extra-intestinal manifestations, early need for corticosteroids (ACG 2019; AGA 2019; AGA 2020).
necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

FOR RENEWALS OF PRIOR AUTHORIZATION FOR ZEPOSIA (OZANIMOD): The determination of medical necessity of a request for renewal of a prior authorization for Zeposia (ozanimod) that was previously approved will take into account whether the beneficiary:

1. Is prescribed Zeposia (ozanimod) by or in consultation with an appropriate specialist (i.e., a neurologist for a diagnosis of multiple sclerosis or a gastroenterologist for a diagnosis of ulcerative colitis); AND

2. Is prescribed a dose that is consistent with FDA-approved package labeling, nationally recognized compendia, or peer-reviewed medical literature; AND

3. Does not have a contraindication to Zeposia (ozanimod); AND

4. For treatment of multiple sclerosis, has documented improvement or stabilization of the multiple sclerosis disease course; AND

5. For treatment of ulcerative colitis, experienced improvement in disease activity and/or level of functioning since starting Zeposia (ozanimod); AND

6. If a prescription for Zeposia (ozanimod) is for a quantity that exceeds the quantity limit, the determination of whether the prescription is medically necessary will also take into account the guidelines set forth in the Quantity Limits Chapter. The list of drugs that are subject to quantity limits, with accompanying quantity limits, is available at: https://www.dhs.pa.gov/providers/Pharmacy-Services/Pages/Quantity-Limits-and-Daily-Dose-Limits.aspx.

NOTE: If the beneficiary does not meet the clinical review guidelines listed above but, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary, the request for prior authorization will be approved.

C. Clinical Review Process

Prior authorization personnel will review the request for prior authorization and apply the clinical guidelines in Section B. above to assess the medical necessity of a prescription for Zeposia (ozanimod). If the guidelines in Section B. are met, the reviewer will prior authorize the prescription. If the guidelines are not met, the prior authorization request will be referred to a physician reviewer for a medical necessity determination. Such a request for prior authorization will be approved when, in the professional judgment of the physician reviewer, the services are medically necessary to meet the medical needs of the beneficiary.

D. References

2. Olek MJ, Mowry E. Disease-modifying therapies for multiple sclerosis: Pharmacology, administration, and adverse effects. In: UpToDate [internet database]. Gonzalez-


Non-Statewide PDL Policies
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group</td>
<td>Off-Label Uses Criteria (Non-Statewide PDL drugs/classes)</td>
</tr>
<tr>
<td>Description</td>
<td>Medications with off-label uses</td>
</tr>
<tr>
<td>Drugs</td>
<td>Off-label uses: Medically accepted indications are defined using the following</td>
</tr>
<tr>
<td></td>
<td>sources: American Hospital Formulary Service-Drug Information (AHFS-DI),</td>
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<td></td>
<td>Truven Health Analytics Micromedex DrugDEX (DrugDEX), National</td>
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<tr>
<td></td>
<td>Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium,</td>
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<td></td>
<td>Wolters Kluwer Lexi-Drugs, and Elsevier/Gold Standard Clinical Pharmacology</td>
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<tr>
<td></td>
<td>and/or positive results from two peer-reviewed published studies.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criterion is met, the request will be approved for up to a 12 month duration</td>
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<td></td>
<td>(depending on the diagnosis and usual treatment duration). If criterion is not met,</td>
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<td>the request will be referred to a Clinician for medical necessity review.</td>
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<tr>
<td>Other Criteria</td>
<td><strong>Authorization:</strong></td>
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<tr>
<td></td>
<td>1. One of the following:</td>
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<td></td>
<td>a. Patient has had a documented trial and or intolerance with up to two</td>
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<td></td>
<td>preferred medications used to treat the documented diagnosis, or for</td>
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<td>medications where there is only one preferred agent, only that agent</td>
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<td></td>
<td>must have been ineffective or not tolerated.</td>
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<td></td>
<td>b. No other formulary medication has a medically accepted use for the patient’s</td>
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<td>specific diagnosis as referenced in the medical compendia</td>
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<td><strong>AND</strong></td>
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<td></td>
<td>2. One of the following:</td>
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<tr>
<td></td>
<td>a. Medication is being requested for an accepted off-label use and is listed</td>
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<td></td>
<td>in the standard clinical decision support resources (as noted in Covered Uses</td>
</tr>
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<td></td>
<td>section above)</td>
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<tr>
<td></td>
<td>b. Requested use can be supported by at least two published peer reviewed</td>
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<td></td>
<td>clinical studies</td>
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<td></td>
<td><strong>AND</strong></td>
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<td></td>
<td>3. Medication is being requested at an appropriate dose per literature</td>
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<td></td>
<td>**Medical Director/clinical reviewer must override criteria when, in his/her</td>
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<td>professional judgement, the requested item is medically necessary.</td>
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<td></td>
<td>Revision/Review Date</td>
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<td></td>
<td>5/2022</td>
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<tr>
<td>Field Name</td>
<td>Field Description</td>
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<td>--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Brand Drug and Non-Specialty Reference Biologics</strong></td>
</tr>
</tbody>
</table>
| Drugs                            | Oral and injectable brand drugs and reference biologics outside of the scope of the PDL when a therapeutic equivalent generic drug or biosimilar/interchangeable biologic is available  

*** The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria***  
*** The Specialty Drugs prior authorization criteria will be applied to specialty drugs without drug or class specific criteria*** |
| Covered Uses                     | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria               | N/A                                                                                                                                                                                                               |
| Required Medical Information     | See “Other Criteria”                                                                                                                                                                                             |
| Age Restrictions                 | N/A                                                                                                                                                                                                               |
| Prescriber Restrictions          | N/A                                                                                                                                                                                                               |
| Coverage Duration                | If all of the conditions are met, requests will be approved for up to 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review. |
| Other Criteria                   | **Brand Drug:**  

- The provider either verbally or in writing has submitted a medical or member specific reason why the brand name drug is required based on the member’s condition or treatment history; **AND**  
- If the member had side effects or a reaction to the generic drug, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drugs. The MedWatch form must be included with the prior authorization request  

**Reference Biologic:**  

- The provider has either verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; **AND** if the member had side effects or a reaction to
| Revision/Review Date | all biosimilar or interchangeable biologics, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drugs. The MedWatch form must be included with the prior authorization request OR
<p>| | • The currently available biosimilar product(s) does not have the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic drug being requested |
| Form FDA 3500 – Voluntary Reporting | <strong>Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</strong> |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
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</thead>
</table>
| Prior Authorization Group Description | **Non-Formulary/Prior Authorization Required Medications (Non-Statewide PDL drugs/classes)**  
**Please Note: If the request is for a non-formulary brand with an A-rated generic, refer to Brand Name Medication Criteria**  
***The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria*** |
| Drugs                             | Non-formulary drugs without drug or class specific prior authorization criteria  
***The Oncology Drugs prior authorization criteria will be applied to oncology drugs without drug or class specific criteria*** |
| Covered Uses                      | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria                | N/A                                                                                                                                                                                                                     |
| Required Medical Information      | See “other criteria”                                                                                                                                                                                                     |
| Age Restrictions                  | N/A                                                                                                                                                                                                                     |
| Prescriber Restrictions           | N/A                                                                                                                                                                                                                     |
| Coverage Duration                 | If the criteria is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration). If criteria is not met, the request will be referred to a Clinician for medical necessity review. |
| Other Criteria                    | **Initial Authorization:**  
- Appropriate diagnosis/indication  
- Appropriate dose of medication based on age (i.e. pediatric and elderly populations) and indication.  
And patient meets one of the three following criteria:  
- Documented trial and failure or intolerance with up to two preferred medications used to treat the documented diagnosis. For medications where there is only one preferred agent, only that agent must have been ineffective or not tolerated.  
- No other preferred medication has a medically accepted use for the patient’s specific diagnosis as referenced in the medical compendia.  
- All other preferred medications are contraindicated based on the patient’s diagnosis, other medical conditions, or other medication therapy.  
Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary. |
<p>| Revision/Review Date              | 5/2022                                                                                                                                                                                                                  |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
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<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Prior Authorization Exception Criteria</strong></td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Scope</td>
<td>Requests for exception to the drug’s prior authorization criteria requirements</td>
</tr>
</tbody>
</table>
| Criteria                   | • The provider either verbally or in writing has submitted a medical or member specific reason why prior authorization criteria all or in part is not applicable to the member.  
  o Medical and/or member specific reasons may include but are not limited to:  
    ▪ Uniqueness of the member’s condition or other physical characteristics of the member’s condition.  
    ▪ Psychiatric, intellectual, physical, cultural, and/or linguistic characteristics of the member which may inhibit the provider from obtaining all necessary prior authorization criteria requirements.  

  *Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.* |
<p>| Coverage Duration          | 12 months                                                                                                                                                                                                       |
| Revision/Review Date:      | 10/2022                                                                                                                                                                                                         |</p>
<table>
<thead>
<tr>
<th><strong>Field Name</strong></th>
<th><strong>Field Description</strong></th>
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</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Quantity Limit Exception Criteria</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td><strong>Covered Uses</strong></td>
</tr>
<tr>
<td>All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.</td>
<td></td>
</tr>
<tr>
<td><strong>Scope</strong></td>
<td>Requests for formulary drugs outside of the PDL exceeding the health plan’s published quantity limits</td>
</tr>
</tbody>
</table>
| **Criteria** | • The provider has submitted a medical reason why the plan’s quantity limit will be inadequate based on the member’s condition and treatment history.  
**AND one of the following:**  
○ The member has a documented treatment failure with the drug prescribed at the health plan’s quantity limit AND the dose requested is supported by the Medical Compendia or current treatment guidelines.  
○ The member requires a dose within prescribing guidelines that exceeds the plan’s quantity limit.  
Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary. |
<p>| <strong>Coverage Duration</strong> | 12 Months |
| <strong>Revision/Review Date</strong> | 10/2022 |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
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</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Safety Edit Exception Criteria</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td>All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Requests for formulary drugs and for previously approved non-formulary drugs outside the scope of the statewide PDL:</td>
</tr>
<tr>
<td></td>
<td>• Exceeding the Food and Drug Administration (FDA) or compendia max dose recommendations</td>
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<td></td>
<td>• Exceeding the FDA dosing or compendia administration frequency recommendations</td>
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<td></td>
<td>• Exceeding the FDA or compendia duration of therapy recommendations</td>
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<tr>
<td></td>
<td>• Duplication of therapy error at Point of Service (POS)</td>
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<tr>
<td></td>
<td>• Age Restriction error at POS</td>
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<tr>
<td></td>
<td>• Day Supply Limit error at POS</td>
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<td></td>
<td>• Concurrent Use error at POS</td>
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<tr>
<td></td>
<td>• Drug Drug Interaction error at POS</td>
</tr>
<tr>
<td>Scope</td>
<td><strong>Exceeding the Food and Drug Administration (FDA) or compendia maximum dose, administration frequency or duration of therapy recommendations.</strong></td>
</tr>
<tr>
<td></td>
<td>• The member must have a documented treatment failure with the drug at the maximum dose based on patient age/weight, administration frequency, or duration of therapy per FDA or compendia.</td>
</tr>
<tr>
<td></td>
<td>AND</td>
</tr>
<tr>
<td></td>
<td>• The provider must submit a medical reason why the maximum dose, administration frequency or duration of therapy needs to be exceeded based on the member’s condition or treatment history.</td>
</tr>
<tr>
<td>Criteria</td>
<td><strong>Duplication of therapy</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Transition from one agent to another</strong></td>
</tr>
<tr>
<td></td>
<td>• If a provider has outlined a plan to transition a member to a similar drug or provided a dose titration schedule, the requested drug is approved for one month*.</td>
</tr>
<tr>
<td></td>
<td><strong>Concurrent Therapy with two similar agents</strong></td>
</tr>
<tr>
<td></td>
<td>• The provider must submit a medical reason why treatment with more than one drug in the same class is required based on the member’s condition and treatment history.</td>
</tr>
<tr>
<td></td>
<td>OR</td>
</tr>
</tbody>
</table>
- The provider must submit disease state specific standard of care guidelines supporting concurrent therapy.

**Age Restriction**

- The provider must submit a medical reason why the drug is needed for a member whose age is outside of the plan’s minimum or maximum age limit.

**AND**

- The indication and dose requested is supported by the Medical Compendia or current treatment guidelines.

**Day Supply Limit**

- An additional fill exceeding the day supply limit is needed based on a dose increase or is needed to achieve a total daily dose

**OR**

- The provider must submit a medical reason why an additional fill is needed outside of the plan’s day supply limit.

**AND**

- The indication and dose requested is supported by the FDA, Medical Compendia or current treatment guidelines.

**Concurrent Use/Drug-Drug Interaction**

- The provider must submit a medical reason why treatment with both drugs is necessary for the member

**AND**

- The increased risk for side effects when taking the drugs together has been discussed with the member

**Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.**

<table>
<thead>
<tr>
<th>Coverage Duration</th>
<th>*One month approval for Duplication of therapy when transitioning from one agent to another and Day Supply Limit due to a dose increase. All Other Scenarios: 12 months</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision/Review Date: 10/2022</td>
<td><strong>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</strong></td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td><strong>Oncology Drugs</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Oral and Injectable Oncology Medications NOT ON THE STATEWIDE PDL (specialty or non-specialty) without medication specific criteria when requested for an oncology diagnosis</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber is an oncologist, or specialist in type of cancer being treated</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved for up to 6 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>All of the following criteria must be met:</strong></td>
</tr>
<tr>
<td></td>
<td>• Requested use must be a labeled indication or be supported by NCCN Category 1 or 2A level of evidence. If the request is for an off-label use supported by NCCN as Category 2B recommendation then medical documentation has been provided as to why member is unable to utilize a treatment regimen with a higher level of evidence (e.g. allergic reaction, contraindication)</td>
</tr>
<tr>
<td></td>
<td>• Documentation has been provided of the results of all required genetic testing where required per drug package insert</td>
</tr>
<tr>
<td></td>
<td>• Documentation has been provided of the results of all required laboratory values and patient specific information (e.g. weight, ALT/AST, Creatine Kinase, etc.) necessary to ensure the patient has no contraindications to therapy per drug package insert</td>
</tr>
<tr>
<td></td>
<td>• The medication is being prescribed at a dose that is within FDA approved/NCCN guidelines.</td>
</tr>
<tr>
<td></td>
<td>• If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following:</td>
</tr>
</tbody>
</table>
|                             | o The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; AND if the member had side effects or a
<table>
<thead>
<tr>
<th>Reaction to the biosimilar or interchangeable biologic, the provider has completed and submitted an FDA MedWatch form to justify the member’s need to avoid these drugs. The MedWatch form must be included with the prior authorization request</th>
</tr>
</thead>
<tbody>
<tr>
<td>- The currently available biosimilar product does not have the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic drug being requested</td>
</tr>
<tr>
<td><strong>Form FDA 3500 – Voluntary Reporting</strong></td>
</tr>
</tbody>
</table>

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Specialty Drugs</strong></td>
</tr>
</tbody>
</table>
| Group Description          | Oral and injectable specialty drugs NOT ON THE STATEWIDE PDL without drug or class specific prior authorization criteria  

*** The Oncology Drugs prior authorization criteria will be applied to oncology drugs NOT ON THE STATEWIDE PDL without drug or class specific criteria***                                                                |
| Drugs                      | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Covered Uses               | N/A                                                                                                                                                                                                                                                                                                                                              |
| Required Medical Information | See “Other Criteria”                                                                                                                                                                                                                                                                                                                                |
| Age Restrictions           | N/A                                                                                                                                                                                                                                                                                                                                              |
| Prescriber Restrictions    | N/A                                                                                                                                                                                                                                                                                                                                              |
| Coverage Duration          | If all of the conditions are met, requests will be approved for up to 6 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.                                                                                   |
| Other Criteria             | • The drug is requested for an appropriate use (per the references outlined in “Covered Uses”)  

• The dose requested is appropriate for the requested use (per the references outlined in “Covered Uses”)  

• If the request is for a non-formulary/non-preferred drug, documentation has been provided that the member has tried and failed two formulary/preferred drugs appropriate for the requested use (per the references outlined in “Covered Uses” or has a medical reason why these drug(s) cannot be used (e.g. intolerance, contraindication)  

• If the request is for a reference biologic drug with either a biosimilar or interchangeable biologic drug currently available, documentation of one of the following:  

  o The provider has verbally or in writing submitted a member specific reason why the reference biologic is required based on the member’s condition or treatment history; **AND** if the member had side effects or a reaction to all biosimilar or interchangeable biologics, the provider has completed and submitted an FDA MedWatch form to justify the
member’s need to avoid these drugs. The MedWatch form must be included with the prior authorization
- The currently available biosimilar product(s) does not have the same appropriate use (per the references outlined in “Covered Uses”) as the reference biologic drug being requested

Form FDA 3500 – Voluntary Reporting

Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Step Therapy Exception Criteria</strong></td>
</tr>
<tr>
<td>Covered Uses</td>
<td>All medically accepted indications. Medically accepted indications are defined using the following compendia resources: the Food and Drug Administration (FDA) approved indication(s) (Drug Package Insert), American Hospital Formulary Service Drug Information (AHFS-DI), and DRUGDEX Information System. The reviewer may also reference disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Scope</td>
<td>Requests for drugs outside the scope of the statewide PDL on the plan’s formulary with a step therapy restriction which do not meet step therapy requirements</td>
</tr>
<tr>
<td>Criteria</td>
<td>Requests for drugs on the plan’s formulary with a step therapy restriction which do not meet step therapy requirements will be considered when the provider verbally or in writing has submitted a medical reason why:</td>
</tr>
<tr>
<td></td>
<td>• Required step therapy drug(s) would be ineffective, or;</td>
</tr>
<tr>
<td></td>
<td>• Required step therapy drug(s) have the potential to cause harm or deterioration of the member’s condition, or;</td>
</tr>
<tr>
<td></td>
<td>• The requested drug would be superior to the required prerequisite trial(s) with preferred drug(s).</td>
</tr>
<tr>
<td>Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
<td></td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>12 Months</td>
</tr>
<tr>
<td>Revision/Review Date:</td>
<td>10/2022</td>
</tr>
<tr>
<td>Prior Authorization Group Description</td>
<td>Anti-amyloid Monoclonal Antibodies (mAb)</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>------------------------------------------</td>
</tr>
<tr>
<td>Drugs</td>
<td>Aduhelm (aducanumab)</td>
</tr>
<tr>
<td><strong>Initial authorizations and reauthorizations must be approved by a Medical Director</strong></td>
<td></td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Patients with moderate to severe Alzheimer’s Disease (AD)</td>
</tr>
<tr>
<td></td>
<td>Patients with neurodegenerative disease caused by other than AD</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>None</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a neurologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>For initial authorization: the request will be approved in accordance with the FDA-indicated titration schedule for up to 6 months</td>
</tr>
<tr>
<td></td>
<td>For reauthorization: if all of the conditions are met, the request will be approved for 6 months.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of mild cognitive impairment (MCI) caused by AD or mild AD</td>
</tr>
<tr>
<td></td>
<td>• The request is for an FDA approved dose</td>
</tr>
<tr>
<td></td>
<td>• Documentation of BOTH of the following:</td>
</tr>
<tr>
<td></td>
<td>o Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan</td>
</tr>
<tr>
<td></td>
<td>o Recent, within past year, baseline Magnetic Resonance Imaging (MRI) scan</td>
</tr>
<tr>
<td></td>
<td>• Clinical Dementia Rating Global (CDR-G) score of 0.5 (very mild dementia)</td>
</tr>
<tr>
<td></td>
<td>• Repeatable Battery for Assessment of Neuropsychological Status (RBANS) delayed memory index (DMI) score ≤ 85 (low average)</td>
</tr>
<tr>
<td></td>
<td>• Mini-Mental State Examination (MMSE) score ≥ 24 (questionably significant impairment)</td>
</tr>
<tr>
<td></td>
<td>• Patient is not taking any chronic medications that can substantially contribute to cognitive impairment (i.e. strong anticholinergics such as first-generation antihistamines,</td>
</tr>
</tbody>
</table>
tricyclic antidepressants; benzodiazepines; antipsychotics; barbiturates; skeletal muscle relaxants; see Beer’s List)

- Not currently using blood thinners (except aspirin)
- No recent (past 1 year) history of stroke or transient ischemic attack (TIA)

**Reauthorization**

- The request is for an FDA approved dose
- Before the 7th and 13th doses, documentation (i.e. chart notes, test results) of repeat MRI scan to monitor for amyloid related imaging abnormalities (ARIA) including the following:
  - Type of ARIA (-edema [E] or hemosiderin deposition [H]), if any
  - Severity of ARIA (mild, moderate, severe), if any
  - If severe ARIA-H, approval of continued therapy is contingent upon repeat MRI demonstrating radiographic stabilization
- CDR-G score of 0.5 (very mild dementia)
- RBANS DMI score ≤ 85 (low average)
- MMSE score of 24-30
- Patient is not taking any medications that can substantially contribute to cognitive impairment (i.e. strong anticholinergics such as first-generation antihistamines, tricyclic antidepressants; benzodiazepines; antipsychotics; barbiturates; skeletal muscle relaxants; see Beer’s List)
- Not currently using blood thinners (except aspirin)
- No recent (past 1 year) history of stroke or TIA
- Recent, within past year, positive results for the presence of beta-amyloid plaques on a positron emission tomography (PET) scan

If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th><strong>Field Name</strong></th>
<th><strong>Field Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Alpha-1 Proteinase Inhibitors (Human)</strong></td>
</tr>
</tbody>
</table>
| Drugs                                  | **Preferred:**
|                                        | Prolastin-C                                                                                                   |
|                                        | **Non-Preferred:**                                                                                           |
|                                        | Aralast NP                                                                                                    |
|                                        | Glassia                                                                                                       |
|                                        | Zemaira                                                                                                       |
|                                        | Or any other newly marketed agent                                                                             |
| Covered Uses                           | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria                     | None                                                                                                          |
| Required Medical Information           | None                                                                                                          |
| Age Restrictions                       | 18 years of age or older                                                                                        |
| Prescriber Restrictions                | Prescribed by or in consultation with a pulmonologist or specialist in the treatment of AAT                  |
| Coverage Duration                      | The request will be approved for up to a 12 month duration.                                                    |
| Other Criteria                         | **Initial Authorization:**
|                                        | • Documented diagnosis of a congenital deficiency of alpha-1 antitrypsin (AAT) (serum AAT level < 11 micromol/L [approximately 57 mg/dL using nephelometry or 80mg/dl by radial immunodiffusion]). |
|                                        | • Documentation was submitted indicating the member has undergone genetic testing for AAT deficiency and is classified as phenotype PiZZ, PiSZ, PiZ(null) or Pi(null)(null) [NOTE: phenotypes PiMZ or PiMS are not candidates for treatment with Alpha1-Proteinase Inhibitors] |
|                                        | • Documentation was submitted (member’s pulmonary function test results) indicating airflow obstruction by spirometry (forced expiratory volume in 1 second [FE\textsubscript{V\textsubscript{1}}] ≤ 65% of predicted), or provider has documented additional medical information demonstrating medical necessity |
|                                        | • Documentation was submitted indicating member is a non-smoker or an ex-smoker (eg. smoking cessation treatment) |
|                                        | • Documentation of the member’s current weight                                                                |
|                                        | • The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage                       |
|                                        | • If the medication request is for an Alpha1-Proteinase Inhibitor (human) product other than Prolastin-C, the patient has a |
documented medical reason (intolerance, hypersensitivity, contraindication, treatment failure, etc.) for not using Prolastin-C to treat their medical condition

Reauthorization:
- Documentation of the member’s current weight
- Documentation was submitted indicating member is a non-smoker or an ex-smoker (e.g. smoking cessation treatment)
- Documentation was submitted indicating the member has clinically benefited from therapy (i.e. stable lung function, improved PFTs, alpha-1 antitrypsin serum level maintained above 11 micromol/L [approximately 57 mg/dL using or 80 mg/dL by radial immunodiffusion], improved quality of life)
- The Alpha-1 Proteinase Inhibitor (human) is being prescribed at an FDA approved dosage

Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Radicava</td>
</tr>
<tr>
<td>Drugs</td>
<td>Radicava, Radivaca ORS (edaravone) and any other newly marketed agent</td>
</tr>
<tr>
<td></td>
<td>*** riluzole (Rilutek) is Preferred and does not require prior authorization***</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a neurologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, requests will be approved for up to 6 month duration</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Member must have a diagnosis of ALS</td>
</tr>
<tr>
<td></td>
<td>• Member must have a documented baseline evaluation of functionality using the revised ALS functional rating scale (ALSFRS-R) score ≥ 2</td>
</tr>
<tr>
<td></td>
<td>• Member’s disease duration is 2 years or less</td>
</tr>
<tr>
<td></td>
<td>• Member has a baseline forced vital capacity (FVC) of ≥ 80%</td>
</tr>
<tr>
<td></td>
<td>• Member has been on riluzole (Rilutek), is beginning therapy as an adjunct to treatment with Radicava, or provider has provided a medical reason why patient is unable to use riluzole</td>
</tr>
<tr>
<td></td>
<td>• Dose is within FDA approved limits</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Member is not ventilator-dependent</td>
</tr>
<tr>
<td></td>
<td>• Provider documents clinical stabilization in symptoms (e.g. stabilization of ALSFRS-R score)</td>
</tr>
<tr>
<td></td>
<td>• Dose is within FDA approved limits</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>4/2023</td>
</tr>
<tr>
<td></td>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
</tr>
<tr>
<td>Prior Authorization Group Description</td>
<td>Amifampridine</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>---------------</td>
</tr>
<tr>
<td>Drugs</td>
<td>Firdapse (amifampridine)</td>
</tr>
</tbody>
</table>

**Covered Uses**
Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.

**Exclusion Criteria**
N/A

**Required Medical Information**
See “Other Criteria”

**Age Restrictions**
Patients must be 6 years age or older

**Prescriber Restrictions**
Prescribed by or in consultation with a neurologist or a neuromuscular specialist

**Coverage Duration**
If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy the request will be approved for 6 months.

**Other Criteria**

**Initial Authorization:**
- Diagnosis of Lambert-Eaton myasthenic syndrome (LEMS) based on at least one electrodiagnostic study (i.e., repetitive nerve stimulation, nerve conduction studies, electromyography) OR anti-P/Q-type voltage-gated calcium channel antibody testing
- Member has been screened for small cell lung cancer (SCLC) and/or other malignancies
- Member does not have a history of seizures
- Medication is being prescribed at an FDA approved dose or is supported by compendia or standard of care guidelines

**Re-authorization:**
- Medication is prescribed at an FDA-approved dose or is supported by compendia or standard of care guidelines
- Documentation provided that prescriber has evaluated the member and recommends continuation of therapy

**Revision/Review Date 1/2023**

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Anti-CD19 CAR-T Immunotherapies</td>
</tr>
<tr>
<td>Drugs</td>
<td>Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel), Tecartus (brexucabtagene autoleucel), Breyanzi (lisocabtagene maraleucel)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Patients with primary central nervous system lymphoma</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be an oncologist, hematologist or other prescribers who specialize in the treatment of lymphoma.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all the criteria are met, the initial request will be approved for a one – time infusion per lifetime.</td>
</tr>
</tbody>
</table>

**Other Criteria**

*Initial authorization:*

- Patient must not have received prior anti-CD19 CAR-T therapy.
- Patient will be screened for HBV, HCV, and HIV in accordance with clinical guidelines.
- Patient does not have an active infection or inflammatory disorder.
- Patient will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment.

**Leukemia**

**B-cell precursor Acute Lymphoblastic Leukemia (ALL):**

- If the request is for Kymriah
  - Patient is 25 years of age or younger
  - ALL that is refractory or in second or later relapse
- If the request is for Tecartus
  - Patient is 18 years of age or older
  - ALL that is relapsed or refractory

**Non-Hodgkin’s Lymphoma (NHL)**

**Mantle Cell Lymphoma (MCL):**

- If the request is for Tecartus:
  - Patient is 18 years of age or older
- Patient has relapsed/refractory disease defined as failure of BOTH the following lines of therapy:
  - Chemoimmunotherapy such as an anti-CD20 monoclonal antibody (e.g. Rituxan) + any chemotherapeutic agent
  - Bruton Tyrosine Kinase (BTK) Inhibitor (e.g. Calquence, Imbruvica, Brukinsa)

### Other forms of NHL:
- If the request is for Breyanzi (lisocabtagene maraleucel), Kymriah (tisagenlecleucel), Yescarta (axicabtagene ciloleucel)
  - Use is supported by a labeled indication or NCCN guidelines
  - Patient is 18 years of age or older
  - For Breyanzi: One of the following:
    - Patient is refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy
    - Patient is refractory to first-line chemoimmunotherapy or relapses after first-line chemoimmunotherapy and is not eligible for hematopoietic stem cell transplantation (HSCT) due to comorbidities or age
    - Patient has failed two or more lines of systemic therapy
  - For Kymriah: Patient has relapsed/refractory disease defined as failure of two or more lines of systemic therapy
  - For Yescarta: Patient refractory to first-line chemoimmunotherapy or relapses within 12 months of first-line chemoimmunotherapy OR has failed two or more lines of systemic therapy

### Re-authorization:
- Treatment exceeding 1 dose per lifetime will not be authorized.

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Prior Authorization Group Description</th>
<th>Anti-FGF23 Monoclonal Antibodies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>Crysvita (burosumab) SQ solution, or any other newly marketed agent</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: The Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>See Other Criteria</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See Other Criteria</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>X-linked hypophosphatemia (XLH): 6 months of age or older Tumor-induced osteomalacia (TIO): 2 years of age and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by, or in consultation with, an endocrinologist, nephrologist, molecular geneticist, or other specialist experienced in the treatment of metabolic bone disorders</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>For X-linked hypophosphatemia (XLH):</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of XLH</td>
</tr>
<tr>
<td></td>
<td>• Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines</td>
</tr>
<tr>
<td></td>
<td>• Labs, as follows:</td>
</tr>
<tr>
<td></td>
<td>o Serum phosphorus below normal for patient age</td>
</tr>
<tr>
<td></td>
<td>o eGFR &gt; 30 mL/min/1.73 m2 or CrCl ≥ 30 mL/min</td>
</tr>
<tr>
<td></td>
<td>• Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)</td>
</tr>
<tr>
<td></td>
<td>• Additionally, for adults:</td>
</tr>
<tr>
<td></td>
<td>o Clinical signs and symptoms of XLH (e.g. bone/joint pain, fractures, osteomalacia, osteoarthritis, ensetopathies, spinal stenosis impaired mobility, presence or history of lower limb deformities, etc.)</td>
</tr>
<tr>
<td></td>
<td>o Trial and failure of, or contraindication to, combination therapy with oral phosphate and active vitamin D (calcitriol) for a minimum of 8 weeks</td>
</tr>
<tr>
<td></td>
<td><strong>For tumor-induced osteomalacia (TIO):</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of FGF23-related hypophosphatemia in TIO</td>
</tr>
</tbody>
</table>
- Dosing is appropriate as per labeling or is supported by compendia or standard of care guidelines
- The tumor(s) is/are not amenable to surgical excision or cannot be located
- Labs, as follows:
  - Serum phosphorus below normal for patient age
  - eGFR > 30 mL/min/1.73 m2 or CrCl ≥ 30 mL/min
- Patient will not use concurrent oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)

**Re-authorization:**

**For XLH or TIO:**
- Documented effectiveness as evidenced by at least one of the following:
  - Serum phosphorus within normal limits for patient age
  - Clinical improvement (e.g. improved rickets, improved bone histomorphometry, increased growth velocity, increased mobility, decrease in bone fractures, improved fracture healing, reduction in bone-related pain)
- 25-hydroxyvitamin D level and, if abnormally low, documented supplementation with cholecalciferol or ergocalciferol
- Patient is not concurrently using oral phosphate and/or active vitamin D analogs (e.g. calcitriol, paricalcitol, doxercalciferol, calcifediol)
- Dosing continues to be appropriate as per labeling or is supported by compendia or standard of care guidelines

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Antisense Oligonucleotides for Duchenne Muscular Dystrophy</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Exondys 51 (eteplirsen), Vyondys 53 (golodirsen), Viltepso (viltolarsen), Amondys 45 (casimersen)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Concomitant use with another antisense oligonucleotide</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by neurologist or provider who specializes in the treatment of DMD</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months and reauthorization requests will be approved for 12 months.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of Duchenne muscular dystrophy (DMD) and lab test was submitted confirming the mutation of dystrophin gene amenable to ONE of the following:</td>
</tr>
<tr>
<td></td>
<td>o Exon 51 skipping for Exondys 51</td>
</tr>
<tr>
<td></td>
<td>o Exon 53 skipping for Vyondys 53 or Viltepso</td>
</tr>
<tr>
<td></td>
<td>o Exon 45 skipping for Amondys 45</td>
</tr>
<tr>
<td></td>
<td>• Baseline results of motor function tests are provided [e.g. 6-Minute Walk Test (6MWT), Time to Stand Test (TTSTAND), Time to Run/Walk Test (TTRW), North Star Ambulatory Assessment (NSAA), Time to Climb 4 Steps Test (TTCLIMB)]</td>
</tr>
<tr>
<td></td>
<td>• Member has concurrent use of corticosteroids unless contraindicated or intolerant</td>
</tr>
<tr>
<td></td>
<td>• Attestation of renal function monitoring is provided with request</td>
</tr>
<tr>
<td></td>
<td>• The request is for an FDA approved dose</td>
</tr>
<tr>
<td>Reauthorization</td>
<td><strong>Reauthorization</strong></td>
</tr>
<tr>
<td></td>
<td>• Has documentation of annual evaluation, including an assessment of motor function ability</td>
</tr>
<tr>
<td></td>
<td>• Based on the prescriber’s assessment the member continues to</td>
</tr>
</tbody>
</table>

Revision/Review Date 4/2023
**Prior Authorization**

**Group Description**

**B-Cell Maturation Antigen (BCMA) Directed Chimeric Antigen Receptor (CAR) T-Cell Therapy**

**Drugs**

Abecma (idecabtagene vicleucel), Carvykti (cilta cabtagene autoleucel)

**Covered Uses**

Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).

**Exclusion Criteria**

N/A

**Required Medical Information**

See “Other Criteria”

**Age Restrictions**

Member must be 18 years or older

**Prescriber Restrictions**

Prescriber must be a hematologist, an oncologist, or other appropriate specialist

**Coverage Duration**

If all the criteria are met, the initial request will be approved for a one–time infusion per lifetime.

**Initial Authorization**

- Member has a diagnosis of relapsed or refractory multiple myeloma (RRMM)
- Member must have received at least 4 prior lines of therapy, which must include ALL of the following:
  - An immunomodulatory agent (e.g. lenalidomide, pomalidomide, thalidomide)
  - A proteasome inhibitor (e.g. bortezomib, carfilzomib, ixazomib)
  - An anti-CD38 monoclonal antibody (e.g. daratumumab, isatuximab)
- Member does not have an active infection
- Member will be screened for cytomegalovirus (CMV), hepatitis B virus (HBV), hepatitis C virus (HCV), and human immunodeficiency virus (HIV) in accordance with clinical guidelines
- Member will not receive live virus vaccines for at least 6 weeks prior to the start of lymphodepleting chemotherapy and until immune recovery following treatment
- Member has not previously received a BCMA CAR-T therapy

**Re-authorization:**

- Treatment exceeding 1 dose per lifetime will not be authorized.

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.

**Revision/Review Date**

7/2022
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Benlysta (belimumab)</td>
</tr>
<tr>
<td>Group Description</td>
<td>Benlysta (belimumab)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Severe active central nervous system lupus</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Must be at least 5 years of age</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a rheumatologist or nephrologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all the criteria are met initial authorization requests may be approved for up to 6 months. Reauthorization requests may be approved for up to 12 months.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Active systemic lupus erythematosus (SLE)</td>
</tr>
<tr>
<td></td>
<td>o Provider attestation that the patient is positive for autoantibodies (or antinuclear antibodies or anti–double-stranded DNA [anti-dsDNA] antibodies)</td>
</tr>
<tr>
<td></td>
<td>o The member has tried and failed both of the following (or contraindication/inability to use these medications):</td>
</tr>
<tr>
<td></td>
<td>▪ Hydroxychloroquine</td>
</tr>
<tr>
<td></td>
<td>▪ One other immunosuppressant [e.g., methotrexate, azathioprine, calcineurin inhibitors or mycophenolate]</td>
</tr>
<tr>
<td></td>
<td>• Active lupus nephritis</td>
</tr>
<tr>
<td></td>
<td>o Provider attestation of diagnosis confirmed by kidney biopsy</td>
</tr>
<tr>
<td></td>
<td>o The member has tried and failed, or has a medical reason for not using, both of the following</td>
</tr>
<tr>
<td></td>
<td>▪ Cyclophosphamide or tacrolimus</td>
</tr>
<tr>
<td></td>
<td>▪ Mycophenolate</td>
</tr>
<tr>
<td></td>
<td>• Provider states the member will not be receiving concomitant therapy with the following:</td>
</tr>
<tr>
<td></td>
<td>o B-cell targeted therapy including (but not limited to) rituximab</td>
</tr>
<tr>
<td></td>
<td>o Interferon receptor antagonist, type 1 including (but not limited to) Saphnelo (anifrolumab)</td>
</tr>
<tr>
<td></td>
<td>• Dosing is appropriate per labeling</td>
</tr>
<tr>
<td>Criteria for Reauthorization</td>
<td><strong>Criteria for Reauthorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documentation or provider attestation of positive clinical response as indicated by one of the following:</td>
</tr>
</tbody>
</table>
| Revision/Review Date: 1/2023 | o Fewer flares that required steroid treatment  
|                            | o Lower average daily oral prednisone dose  
|                            | o Improved daily function either as measured through a validated functional scale or through improved daily performance documented at clinic visits  
|                            | o Sustained improvement in laboratory measures of lupus activity  
|                            | • Dosing is appropriate per labeling  

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
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<thead>
<tr>
<th>Field Name</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Blincyto</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Blincyto (blinatumomab)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restriction</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be an oncologist/hematologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>The request will be approved for up to a 12 month duration.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient has a diagnosis of one of the following forms of Acute Lymphoblastic Leukemia (ALL):</td>
</tr>
<tr>
<td></td>
<td>a) Relapsed CD19-positive B-cell precursor ALL</td>
</tr>
<tr>
<td></td>
<td>b) Refractory CD19-positive B-cell precursor ALL</td>
</tr>
<tr>
<td></td>
<td>c) B-cell precursor CD-positive ALL in first or second complete remission with minimal residual disease (MRD) greater than or equal to 0.1</td>
</tr>
<tr>
<td></td>
<td>• Provider attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient has a diagnosis of relapsed or refractory CD19-positive B-cell precursor ALL and has not exceeded 9 total cycles of Blincyto therapy</td>
</tr>
<tr>
<td></td>
<td>• Provider attests to treatment response or stabilization of disease</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests to monitor patient for Cytokine Release Syndrome (CRS) and neurological toxicities</td>
</tr>
<tr>
<td></td>
<td><em><strong>For CD19-positive B-cell precursor ALL with MRD, reauthorization is not allowed</strong></em></td>
</tr>
<tr>
<td></td>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>1/2023</td>
</tr>
<tr>
<td><strong>Field Name</strong></td>
<td><strong>Field Description</strong></td>
</tr>
<tr>
<td>--------------------------------</td>
<td>-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Brineura (cerliponase alfa)</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Brineura (cerliponase alfa)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert, and/or per the National Comprehensive Cancer Network (NCCN)</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Member must be 3 years of age or older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a neurologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved for 6 months.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documentation of confirmed diagnosis of late infantile neuronal ceroid lipofuscinos type 2 (CLN2) with one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Lab results demonstrating deficient TPP1 enzyme activity</td>
</tr>
<tr>
<td></td>
<td>o Identification of causative mutations in the TPP1/CLN2 gene</td>
</tr>
<tr>
<td></td>
<td>• Documentation of baseline CLN2 Clinical Rating Scale motor +language score.</td>
</tr>
<tr>
<td></td>
<td>• Prescribed dose is consistent with FDA-approved labeling</td>
</tr>
<tr>
<td></td>
<td><strong>Re-authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient’s disease course has stabilized or improved based on the prescriber’s assessment</td>
</tr>
<tr>
<td></td>
<td>• Prescribed dose is consistent with FDA-approved labeling</td>
</tr>
<tr>
<td></td>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</td>
</tr>
</tbody>
</table>

**Revision/Review Date:** 7/2022
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Ileal bile acid transporter inhibitor (IBAT)</td>
</tr>
<tr>
<td>Group Description</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>Bylvay (odevixibat), Livmarli (maralixibat)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Bylvay: 3 months and older</td>
</tr>
<tr>
<td></td>
<td>Livmarli: 1 year and older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a gastroenterologist or hepatologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the conditions are met, the request will be approved for a 6 month duration for initial requests and a 12 month duration for renewal requests.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Progressive Familial Intrahepatic Cholestasis (Bylvay ONLY)</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of progressive familial intrahepatic cholestasis (PFIC) type 1, 2, or 3 with genetic confirmation</td>
</tr>
<tr>
<td></td>
<td>• Documentation that patient does not have an ABCB11 variant that results in non-functional or complete absence of bile salt export pump protein (BSEP-3)</td>
</tr>
<tr>
<td></td>
<td>• Documented history of moderate to very severe pruritus</td>
</tr>
<tr>
<td></td>
<td>• Documentation of patient’s weight</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment</td>
</tr>
<tr>
<td></td>
<td>• Baseline serum bile acid level is provided</td>
</tr>
<tr>
<td></td>
<td>• Documentation of trial and failure OR contraindication to at least ONE of the following:</td>
</tr>
<tr>
<td></td>
<td>• Ursodiol</td>
</tr>
<tr>
<td></td>
<td>• Cholestyramine or colesevelam</td>
</tr>
<tr>
<td></td>
<td>• The prescribed dose is within FDA approved dosing guidelines</td>
</tr>
<tr>
<td></td>
<td><strong>Alagille Syndrome (Livmarli ONLY)</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Alagille syndrome (ALGS)</td>
</tr>
<tr>
<td></td>
<td>• Documented history of moderate to very severe pruritus</td>
</tr>
<tr>
<td></td>
<td>• Documentation of trial and failure OR medical reason why the member is unable to use all of the following:</td>
</tr>
</tbody>
</table>
- Ursodiol
- Cholestyramine or colesevelam
- Rifampin
- Prescriber attests that the member has cholestasis
- Baseline serum bile acid level is provided
- Documentation of patient’s weight
- Prescriber attests to monitor liver function tests and fat soluble vitamin (FSV) levels during treatment
- The prescribed dose is within FDA approved dosing guidelines

**Reauthorization:**
- Documentation of clinical benefit indicating each of the following:
  - An improvement in pruritus (e.g. improved observed scratching, decreased sleep disturbances/nighttime awakenings due to scratching, etc.)
  - Reduction in serum bile acid level from baseline
- Documentation of patient’s weight
- Prescriber attests to monitor liver function tests and FSV levels during treatment
- Prescriber attests that patient has had no evidence of hepatic decompensation (e.g. variceal hemorrhage, ascites, hepatic encephalopathy, portal hypertension, etc.)
- The prescribed dose is within FDA approved dosing guidelines

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Camzyos</td>
</tr>
<tr>
<td>Group Description</td>
<td>Camzyos (mavacamten)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a cardiologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
</tbody>
</table>
| Other Criteria                   | **Initial Authorization:**  
  - Diagnosis of symptomatic New York Heart Association (NYHA) class II or III obstructive hypertrophic cardiomyopathy (oHCM)  
  - Patient has a left ventricular ejection fraction (LVEF) ≥55%  
  - Patient has a peak left ventricular outflow tract (LVOT) gradient ≥50 mmHg at rest or with provocation  
  - Trial and failure, contraindication or intolerance to one agent from BOTH of the following:  
    - Beta blockers (i.e. metoprolol, propranolol, atenolol)  
    - Non-dihydropyridine calcium channel blockers (i.e. verapamil, diltiazem)  
  - Prescriber attests that patient is not diagnosed with a disorder that causes cardiac hypertrophy that mimics oHCM (i.e., Fabry disease, amyloidosis, or Noonan syndrome with LV hypertrophy)  
  - Prescriber attests that patient is not using moderate to strong CYP2C19 or CYP3A4 inhibitors or inducers  
  - Medication is prescribed at an FDA approved dose  
  **Re-Authorization:**  
  - Documentation of clinical benefit as evidenced by an improvement in oHCM symptoms (i.e., improvement in shortness of breath, LVOT, peak oxygen consumption, etc.) from baseline OR improvement or no worsening of NYHA functional class from baseline |
Date: 7/2022

- Patient has a left ventricular ejection fraction (LVEF) ≥50%
- Medication is prescribed at an FDA approved dose

If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Compound Products</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td>Compounds over $500, compounds that include one or more ingredients that are non-formulary/require prior authorization, or compounds that have a safety edit on any ingredient.</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criterion is met, the request will approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration). If criterion is not met, the request will be referred to a Clinician for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Clinical rationale for using a compound product instead of an FDA approved product has been provided AND</td>
</tr>
<tr>
<td></td>
<td>• Peer reviewed medical literature supporting use of compounded product for the indication being requested has been provided AND</td>
</tr>
<tr>
<td></td>
<td>• For drugs included in the Statewide PDL, requirements from the associated Statewide PDL Prior Authorization Guidelines also apply if they are applicable to the indication being requested.</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td><strong>Reauthorization:</strong></td>
</tr>
<tr>
<td>1/2023</td>
<td>• Provider attests that patient has clinical improvement associated with use of compound product</td>
</tr>
<tr>
<td></td>
<td><strong>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</strong></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Continuous Glucose Monitors</td>
</tr>
</tbody>
</table>
| Group Description          | **Drugs**<br>PREFERRED: Freestyle Libre 14 Day, Freestyle Libre 2, FreeStyle Libre 3, Dexcom G6, Dexcom G7  <br>NON-PREFERRED: Eversense  <br>(Sensor, Transmitter, and Reader components)  <br>And any newly marketed product in this class  
**This policy does not apply to continuous glucose monitor/insulin pump combination products reviewed and/or covered by the Medical Benefit including, but not limited to, the MiniMed. Requests for these products are referred to the plan’s Utilization Management team for Review** |
| Covered Uses               | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria         | Diabetes not treated with insulin                                                                                                                                                                                                                                                                                                               |
| Required Medical Information | See “Other Criteria”                                                                                                                                                                                                                                                                                                                              |
| Age Restrictions           | Patient must be age appropriate per prescribing information (PI)                                                                                                                                                                                                                                                                                  |
| Prescriber Restrictions    | N/A                                                                                                                                                                                                                                                                                                                                                  |
| Coverage Duration          | If all of the criteria are met, the request will be approved for 12 months.                                                                                                                                                                                                                                                                       |
| Other Criteria             | - Diagnosis – diabetes  
- Treatment with insulin  
- If the request is for a non-preferred product, trial and failure of or medical reason why patient cannot use a preferred product.  
- If member is continuing use of a non-preferred CGM, trial of a preferred CGM first is not required                                                                                                                                                                             |
<p>| Revision/Review Date       | Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.                                                                                                                                                                                                      |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Corlanor</td>
</tr>
<tr>
<td>Group Description</td>
<td>Corlanor (ivabradine)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Pregnancy</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a cardiologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the conditions are met, the request will be approved for 12 month duration.</td>
</tr>
</tbody>
</table>
| Other Criteria              | **Heart Failure in Adult Patients:**  
1. Member is aged 18 years or older  
2. Member has a diagnosis of stable symptomatic chronic heart failure (NYHA functional class II-IV) with a left ventricular ejection fraction ≤ 35%  
3. Member is in sinus rhythm with a resting heart rate ≥ 70 beats per minute (bpm)  
4. Member is currently being prescribed, or documentation has been provided that the member is not able to tolerate, an evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate) at maximally tolerated dose  

**Heart Failure in Pediatric Patients:**  
1. Member is aged 6 months to less than 18 years of age  
2. Member has stable heart failure (NYHA/Ross functional class II-IV) due to dilated cardiomyopathy and a left ventricular ejection fraction ≤ 45%  
3. Member is in sinus rhythm with an elevated resting heart rate  

<table>
<thead>
<tr>
<th>Revision/Review Date</th>
<th>1/2023</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</td>
<td></td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
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<tr>
<td>-------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>Corticotropin</td>
</tr>
<tr>
<td>Group Description</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td><strong>Preferred:</strong> Cortrophin (corticotropin)  &lt;br&gt; <strong>Non-Preferred:</strong> Acthar (corticotropin)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved for up to a 1 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Infantile Spasms (West Syndrome):</strong>  &lt;br&gt; • Patient is &lt; 2 years of age  &lt;br&gt; • The medication is being prescribed by a neurologist.  &lt;br&gt; • Documentation of the patient’s current weight (in kg) and height/length (in cm) or body surface area (BSA)</td>
</tr>
<tr>
<td></td>
<td><strong>Multiple Sclerosis:</strong>  &lt;br&gt; • Documentation was submitted that patient is having an acute attack, with neurologic symptoms and increased disability or impairments in vision, strength or cerebellar function, and has failed therapy with intravenous (IV) methylprednisolone, or a medical reason has been submitted why patient is unable to use IV methylprednisolone.  &lt;br&gt; • The medication is being prescribed by a neurologist  &lt;br&gt; • If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product</td>
</tr>
<tr>
<td></td>
<td><strong>All Other FDA Approved Conditions and Indications:</strong>  &lt;br&gt; • Documented trial and failure of an IV corticosteroid AND an oral corticosteroid, or documented medical reason for why the patient cannot use these therapies for treatment  &lt;br&gt; • Documentation was provided that ALL other standard therapies have been used to treat the member’s condition as described in the medical compendium (Micromedex, AHFS, Drug Points, and package insert) as defined in the Social Security Act and/or per recognized standard of care</td>
</tr>
</tbody>
</table>
| Revision/Review Date | guidelines OR there is a documented medical reason (i.e. medical intolerance, treatment failure, etc.) for why all other standard therapies could not be used to treat the member’s condition.  
• Prescriber is a specialist in the condition they are treating.  
• If the request is for a non-preferred product, trial and failure of, contraindication to, or medical reason for not using the preferred product  

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.** |
<table>
<thead>
<tr>
<th>Prior Authorization Group Description</th>
<th><strong>Cystic Fibrosis transmembrane conductance regulator (CFTR) Modulators</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug(s)</strong></td>
<td>Kalydeco, Kalydeco Granules (ivacaftor), Orkambi, Orkambi Granules (lumacaftor/ivacaftor), Symdeko (tezacaftor/ivacaftor), Trikafta (elexacaftor/tezacaftor/ivacaftor), or any newly marketed CFTR modulator to treat cystic fibrosis</td>
</tr>
<tr>
<td><strong>Covered Uses</strong></td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), and/or per standard of care guidelines.</td>
</tr>
<tr>
<td><strong>Exclusion Criteria</strong></td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td><strong>Required Medical Information</strong></td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td><strong>Age Restrictions</strong></td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td><strong>Prescriber Restrictions</strong></td>
<td>Prescriber is pulmonologist or specializes in the treatment of cystic fibrosis</td>
</tr>
<tr>
<td><strong>Coverage Duration</strong></td>
<td>If all of the conditions are met the initial request will be 6 months. Reauthorization requests will be 12 months.</td>
</tr>
</tbody>
</table>
| **Other Criteria**                   | **Initial criteria:**  
|                                     | • Documentation provided includes a copy of the FDA-cleared cystic fibrosis (CF) mutation test OR documentation from the National Cystic Fibrosis Registry (e.g. screen shot) with member’s genetic mutations  
|                                     | • The request is for an FDA approved indication for the member’s genotype and within dosing guidelines  
|                                     | • The request is appropriate for member (e.g. age/weight) based on FDA-approved package labeling, peer reviewed medical literature and nationally-recognized compendia. |
| **Review/Revision Date**             | **Reauthorization:**  
|                                     | • Based on prescriber’s assessment, patient continues to benefit from therapy  
<p>|                                     | • The request is within FDA dosing guidelines |
|                                     | <strong>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</strong> |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Danazol</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td><strong>Danazol capsules</strong></td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>According to package insert</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved with a 6 month duration for generic medication; if the criteria are not met, the request will be referred to a Medical Director for medical necessity review.</td>
</tr>
</tbody>
</table>
| Other Criteria                   | **ENDOMETRIOSIS**  
  o Diagnosis of endometriosis  
  o One of the following:  
    o Documented trial and failure or medical reason for not using an analgesic pain reliever (e.g., NSAIDs, COX-2 inhibitors) taken in combination with a hormonal contraceptive (e.g. estrogen/progestin, progestin only)  
    o Documented trial and failure of a gonadotropin-releasing hormone (GnRH) agonists or a GNRH antagonist.  
    o Prescribing physician is a gynecologist.  

**HEREDITARY ANGIOEDEMA:**  
  o Diagnosis of hereditary angioedema.  
  o Prescriber is an immunologist, allergist, rheumatologist, or hematologist  

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.  

Revision/Review Date 10/2022
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Daraprim</td>
</tr>
<tr>
<td>Drugs</td>
<td>pyrimethamine (Daraprim)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Patients with documented megaloblastic anemia due to folate deficiency.</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be an appropriate specialist or documentation has been provided that prescriber has consulted with an appropriate specialist (i.e. infectious disease, OB/GYN).</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the conditions are met, congenital toxoplasmosis requests will be approved for 12 months, and all other requests will be approved for 3 months-at a time. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
</tbody>
</table>
| Other Criteria              | **Congenital Toxoplasmosis**  
  • Diagnosis of congenital toxoplasmosis                                                                                                                |
|                             | **Acquired Toxoplasmosis**  
  • Diagnosis of acquired toxoplasmosis  
  • Prescribed in combination with leucovorin and either a sulfonamide or clindamycin                                                                     |
|                             | **Patients with Human Immunodeficiency Virus (HIV)/Acquired Immunodeficiency Syndrome (AIDS)**  
  • Diagnosis of Toxoplasmosis  
  OR  
  • Both of the following:  
    o Medication is being prescribed for one of the following:  
      ▪ Toxoplasmosis prophylaxis  
      ▪ Cystoisosporiasis  
      ▪ Pneumocystis jiroveci pneumonia prophylaxis/treatment  
    o Documented medical reason why (e.g. intolerance, hypersensitivity, contraindication) sulfamethoxazole/trimethoprim cannot be used |
|                             | **Hematopoietic Cell Transplantation Recipients**  
  • Medication prescribed for Toxoplasmosis prophylaxis  
  • Documentation of medical reason why sulfamethoxazole/trimethoprim cannot be used  
  Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary. |
<p>| Revision/Review Date        | 10/2022                                                                                                                                                                                                          |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Diagnosis Code Requirement</td>
</tr>
</tbody>
</table>
| Group Description                  | Formulary/preferred medications that will pay at point of sale if the required ICD-10 code is submitted at the pharmacy  
1. Elmiron (N30.11 or N30.10)                                                                                                  |
<p>| Drugs                              | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Covered Uses                       |                                                                                           |
| Exclusion Criteria                 | N/A                                                                                                                                                                                                                                                                                                                                               |
| Required Medical Information       | See “other criteria”                                                                                                                                                                                                                                                                                                                                 |
| Age Restrictions                   | N/A                                                                                                                                                                                                                                                                                                                                               |
| Prescriber Restrictions            | N/A                                                                                                                                                                                                                                                                                                                                               |
| Coverage Duration                  | If the criterion is met, the request will be approved for up to a 12 month duration (depending on the diagnosis and usual treatment duration). If criterion is not met, the request will be referred to a Clinician for medical necessity review.                                                                                     |
| Other Criteria                     | Provider has submitted a diagnosis that is FDA approved or referenced in disease state specific standard of care guidelines for the requested drug. (Please see covered uses section for appropriate sources)                                                                                                           |
| Revision/Review Date 5/2022        | Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.                                                                                                                                                                                                 |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Fabrazyme</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td><strong>Fabrazyme (agalsidase beta)</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Members should be greater than or equal to 2 years of age</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td><strong>Initial Authorization:</strong> If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.</td>
</tr>
</tbody>
</table>
| Other Criteria                 | **Initial Authorization:**  
  - Male members must have a documented diagnosis of Fabry disease confirmed by one of the following:  
    1. An undetectable (<3%) alpha galactosidase A (alpha-Gal-A) activity level OR  
    2. A deficient (3-35%) alpha-Gal- activity level AND a documented detection of pathogenic mutations in the galactosidase alpha (GLA) gene by molecular genetic testing  
  - Female members must have a documented diagnosis of Fabry disease confirmed by detection of pathogenic mutations in the GLA gene by molecular genetic testing AND evidence of clinical manifestation of the disease (e.g. kidney, neurologic, cardiovascular, gastrointestinal)  
  - Member must not be using concurrently with Galafold (migalastat)  
  - Documentation of the member’s current weight  
  - Request is for an FDA-approved dose  

  **Re-Authorization:**
<table>
<thead>
<tr>
<th><strong>Revision/Review Date:</strong> 10/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>• Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function, or has remained asymptomatic</strong></td>
</tr>
<tr>
<td><strong>• Member must not be using concurrently with Galafold (migalastat)</strong></td>
</tr>
<tr>
<td><strong>• Documentation of the member’s current weight</strong></td>
</tr>
<tr>
<td><strong>• Request is for an FDA-approved dose</strong></td>
</tr>
</tbody>
</table>

If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.

**Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Filspari (sparsentan)</td>
</tr>
<tr>
<td>Group Description</td>
<td>Filspari (sparsentan)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Filspari (sparsentan)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
</tbody>
</table>
| Exclusion Criteria               | • Pregnancy  
• Coadministration with renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists, or aliskiren |
| Required Medical Information     | See “Other Criteria”                                                                                                                                                                                                                                                                                                                                |
| Age Restrictions                 | According to package insert                                                                                                                                                                                                                                                                                                                          |
| Prescriber Restrictions          | Prescriber must be a nephrologist or in consultation with a nephrologist                                                                                                                                                                                                                  |
| Coverage Duration                | If all of the criteria are met, the initial request will be approved for 9 months. For continuation of therapy, the request will be approved for 12 months.                                                                                                                                                                                                 |
| Other Criteria                   | **Initial Authorization:**  
• Medication is prescribed at an FDA approved dose  
• Diagnosis of primary immunoglobulin A nephropathy (IgAN) verified by biopsy  
• Total urine protein ≥1.0 g/day  
• eGFR ≥30 mL/min/1.73 m²  
• Trial and failure with a maximized stable dose of ACE inhibitor or ARB  

**Re-Authorization:**  
• Documentation of positive clinical response as evidenced by a decrease in urine protein-to-creatinine ratio (UPCR)  
• Medication is prescribed at an FDA approved dose  

Date: 4/2023  
If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Primary Hemophagocytic Lymphohistiocytosis (HLH) Agents</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Gamifant (emapalumab-lzsg)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Members who have undergone hematopoietic stem cell transplantation (HSCT)</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>“See Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Hematologist, Oncologist, Immunologist, Transplant Specialist, or other specialist experienced in the treatment of immunologic disorders</td>
</tr>
</tbody>
</table>
| Coverage Duration           | Initial Authorization: 1 month  
Reauthorization: 3 months                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| Other Criteria              | *Gamifant will only be approved for members who have not yet received HSCT and will be discontinued at the initiation of HSCT*  
**Initial Authorization**  
- Member has a diagnosis of Primary HLH  
- Prescriber attests that member has not achieved a satisfactory response to or is intolerant to conventional HLH therapy (e.g. etoposide, dexamethasone) or has recurrent disease  
- Prescriber attests that the member is a candidate for hematopoietic stem cell transplant (HSCT)  
- Member has been screened for latent tuberculosis infection  
- Member has or will receive prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections  
- Dosing is consistent with FDA approved labeling  

**Reauthorization**  
- Member continues to meet initial authorization criteria  
- Member is receiving prophylactic pre-medications (e.g. antivirals, antibiotics, antifungals) for Herpes Zoster, *Pneumocystis jirovecii*, and other fungal infections
<p>| Revision/Review Date | Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary. |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Galafold</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>Galafold (migalastat)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Members should be greater than or equal to 18 years of age</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a geneticist, cardiologist, nephrologist or specialist experienced in the treatment of Fabry disease</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td><strong>Initial Authorization:</strong> If the criteria are met, the request will be approved for a 6-month duration. Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.</td>
</tr>
</tbody>
</table>
| Other Criteria                 | **Initial Authorization:**  
  • Member has a documented diagnosis of Fabry disease  
  • Documentation member has an amenable galactosidase alpha (GLA) gene variant based on in vitro assay data  
  • Member will not be using Galafold concurrently with enzyme replacement therapy (e.g., Fabrazyme)  
  • Documented baseline eGFR $\geq$ 30 mL/min  
  • Request is for an FDA-approved dose  
  **Re-Authorization:**  
  • Documentation that member has experienced an improvement in symptoms from baseline including but not limited to: decreased pain, decreased gastrointestinal manifestations, decrease in proteinuria, stabilization of increase in eGFR, reduction of left ventricular hypertrophy (LVH) on echocardiogram, or improved myocardial function  
  • Member must not be using concurrently with other enzyme replacement therapy (e.g., Fabrazyme)  
  • Documented eGFR $\geq$ 30 mL/min  
  • Request is for an FDA-approved dose |
<table>
<thead>
<tr>
<th>Revision/Review Date:</th>
<th>10/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</td>
<td></td>
</tr>
<tr>
<td><strong>Physician/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</strong></td>
<td></td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td><strong>Glycopyrrolate (oral)</strong></td>
</tr>
</tbody>
</table>
| Drugs                | **Formulary Status:** Formulary; Pays at point-of-sale  
glycopyrrolate 1, 2 mg tablet  
**Formulary Status:** Requires prior authorization  
Glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution  
Glycopyrrolate (Glycate) 1.5 mg tablet  
Dartisla ODT (glycopyrrolate) 1.7 mg orally disintegrating tablet |
| Covered Uses         | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria   | N/A                                                                                                                                                                 |
| Required Medical     | See “other criteria”                                                                                                                                                   |
| Information          |                                                                                                                                                                      |
| Age Restrictions     | Per package insert                                                                                                                                                   |
| Prescriber Restrictions | N/A                                                                                                              |
| Coverage Duration    | If the criteria are met, the request will be approved with up to a 12 month.                                                                                       |
| Other Criteria       | **Requests for glycopyrrolate (Cuvposa) 1 mg/5 mL oral solution:**  
  • Documented diagnosis of chronic severe drooling  
  **AND**  
  • Documented neurological condition associated with problem drooling (e.g., cerebral palsy)  
  **AND**  
  • Member has tried and failed non-pharmacologic approaches to treatment (e.g., correction of situational factors, treatment of dental malocclusion and caries, orthodontic appliances, swallowing therapy, biofeedback and automatic cueing, positive and negative reinforcement)  
  **AND**  
  • Drug is being prescribed at FDA approved dose  
**Requests for Dartisla ODT or glycopyrrolate 1.5 mg tablet:**  
  • Documented diagnosis of peptic ulcer disease  
  **AND**  
  • Glycopyrrolate will be used as an adjunct to other therapies |
<table>
<thead>
<tr>
<th>Revision/Review Date</th>
<th>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</th>
</tr>
</thead>
</table>
| 1/2023               | **AND**  
|                      | • Member has tried and failed glycopyrrolate 1 mg or 2 mg tablets or has a medical reason (e.g. intolerance, hypersensitivity, contraindication, etc.) for not using glycopyrrolate 1 mg and 2 mg tablets  
|                      | **AND**  
|                      | • Drug is being prescribed at and FDA approved dose |


<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Gene Therapy for Hemophilia</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Hemgenix (etranacogene dezaparvovec)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Patient has previously received this medication</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Patient must be 18 years of age or older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a hematologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all the criteria are met, the initial request will be approved for a one-time treatment.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of Hemophilia B (congenital Factor IX deficiency) with ONE of the following:</td>
</tr>
<tr>
<td></td>
<td>o Currently using Factor IX prophylaxis therapy</td>
</tr>
<tr>
<td></td>
<td>o Has current or historical life-threatening hemorrhage</td>
</tr>
<tr>
<td></td>
<td>o Has repeated, serious spontaneous bleeding episodes</td>
</tr>
<tr>
<td></td>
<td>• Documentation that patient has ≤2% of normal circulating Factor IX)</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests they have performed liver health assessments, including enzyme testing and hepatic ultrasound and elastography</td>
</tr>
<tr>
<td></td>
<td>• Documented Factor IX inhibitor titer test showing the patient is negative for Factor IX inhibitors</td>
</tr>
<tr>
<td></td>
<td>• Patient’s weight</td>
</tr>
<tr>
<td></td>
<td>• Medication is prescribed at an FDA approved dose</td>
</tr>
<tr>
<td>Date: 1/2023</td>
<td>The safety and effectiveness of repeat administration of Hemgenix have not been evaluated and will not be approved.</td>
</tr>
<tr>
<td></td>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>Topical mTOR Kinase Inhibitors</td>
</tr>
<tr>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>Hyftor (sirolimus topical gel)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Member concomitantly taking an oral mTOR inhibitor</td>
</tr>
<tr>
<td>Required Medical</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Information</td>
<td></td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Member must be 6 years or older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a dermatologist, medical geneticist, neurologist, or other prescriber who specializes in the treatment of genetic or dermatologic disorders.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, requests will be approved with up to a 3 month duration. Thereafter, reauthorization requests will be approved with up to a 6 month duration.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Member has a confirmed diagnosis of tuberous sclerosis complex (TSC)</td>
</tr>
<tr>
<td></td>
<td>• Member has at least 3 facial angiofibromas measuring 2 mm or larger in diameter</td>
</tr>
<tr>
<td></td>
<td>• Documentation of a comprehensive dermatologic evaluation has been provided</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests that the member is not a candidate for laser therapy or surgery</td>
</tr>
<tr>
<td></td>
<td>• Medication is being prescribed at an FDA approved dose</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documentation has been provided indicating that the member has experienced a clinical benefit from treatment (e.g. improvement in size and color of angiofibromas)</td>
</tr>
<tr>
<td></td>
<td>• Documentation of a comprehensive dermatologic evaluation has been provided</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests that the member is not a candidate for laser therapy or surgery</td>
</tr>
<tr>
<td></td>
<td>• Medication is being prescribed at an FDA approved dose</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>4/2023</td>
</tr>
<tr>
<td>Prior Authorization Group Description</td>
<td>Imcivree (setmelanotide)</td>
</tr>
<tr>
<td>---------------------------------------</td>
<td>-------------------------</td>
</tr>
<tr>
<td>Drugs</td>
<td>Imcivree (setmelanotide)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Age appropriate per labeling</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with medical geneticist, endocrinologist, or specialist in metabolic disorders</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved for 6 months, or 12 months for BBS.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Requested dose is appropriate per labeling</td>
</tr>
<tr>
<td></td>
<td>• Documentation of current weight and body mass index (BMI)</td>
</tr>
</tbody>
</table>
|                                       | • BMI/weight must be one of the following:
|                                       | 1. BMI of 27 - 29.9 kg/m\(^2\) with one of the following weight-related comorbidities: coronary artery disease, diabetes, hypertension, dyslipidemia, or obstructive sleep apnea |
|                                       | 2. BMI of 30 kg/m\(^2\) or more |
|                                       | 3. For pediatric patients with: |
|                                       |   - POMC, PCSK1, or LEPR Deficiency: weight must be ≥ 95th percentile for age on growth chart assessment |
|                                       |   - Bardet-Biedl syndrome: weight must be ≥ 97th percentile for age on growth chart assessment |
|                                       | • Documentation of counseling regarding lifestyle changes and behavioral modification (e.g. healthy diet and increased physical activity) For Imcivree, the patient meets one of the following:
<p>|                                       | 1. Diagnosis of Bardet-Biedl syndrome (BBS) |
|                                       | 2. Obesity is related to proopiomelanocortin (POMC), proprotein convertase subtilisin/kexin type 1 (PCSK1), or leptin receptor (LEPR) deficiency |
|                                       | <strong>AND</strong> |
|                                       | • Documentation of genetic testing confirming variants in POMC, PCSK1, or LEPR genes that are interpreted as pathogenic, likely pathogenic, or of uncertain significance (cases with variants classified as benign or likely benign may not be approved) |
|                                       | <strong>Re-Authorization:</strong> |
|                                       | • Documentation of at least 5% reduction in body weight compared with baseline or 5% of baseline BMI for patients with continued growth potential |
| Revision/Review Date: 4/2023 | Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary. |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group</td>
<td><strong>Immune Globulins</strong></td>
</tr>
<tr>
<td>Brand Name</td>
<td>Gamunex-C (IV or SQ) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Bivigam (IV) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Cuvitru (SQ) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Flebogamma (IV) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Gamastan (IM) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Gamastan SD (IM) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Gammagard liquid (IV or SQ) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Gammagard SD (IV) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Gammaked (IV or SQ) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Gammmaplex (IV) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Hizentra (SQ) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Octagam (IV) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Privigen (IV) (Immune Globulin)</td>
</tr>
<tr>
<td></td>
<td>Asceniv (IV) (Immune Globulin-slra)</td>
</tr>
<tr>
<td></td>
<td>Cutaquig (SQ) (Immune Globulin-hipp)</td>
</tr>
<tr>
<td></td>
<td>Panzyga (IV) (Immune Globulin-ifas)</td>
</tr>
<tr>
<td></td>
<td>Hyqvia (SQ) (Immune Globulin Human/Recombinant Human Hyaluronidase)</td>
</tr>
<tr>
<td></td>
<td>Xembify (SQ) (Immune Globulin-klhw)</td>
</tr>
<tr>
<td></td>
<td>Or any newly marketed immune globulin</td>
</tr>
<tr>
<td><strong>Gamunex-C is the preferred product for the indications of</strong></td>
<td><strong>primary immunodeficiency, chronic idiopathic</strong></td>
</tr>
<tr>
<td></td>
<td><strong>thrombocytopenic purpura, and chronic inflammatory</strong></td>
</tr>
<tr>
<td></td>
<td><strong>demyelinating polyneuropathy</strong></td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food</td>
</tr>
<tr>
<td></td>
<td>and Drug Administration (FDA), Micromedex, American Hospital Formulary Service</td>
</tr>
<tr>
<td></td>
<td>(AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional</td>
</tr>
<tr>
<td></td>
<td>(USP DI), the Drug Package Insert (PPI), or disease state specific standard of care</td>
</tr>
<tr>
<td></td>
<td>guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>According to package insert</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met the request will be approved for a 3 month duration unless</td>
</tr>
<tr>
<td></td>
<td>otherwise specified in the diagnosis specific “Other Criteria” section below.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>All Requests:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documentation of diagnosis confirmed by a specialist</td>
</tr>
<tr>
<td></td>
<td>• Member has tried and failed, or has a documented medical</td>
</tr>
</tbody>
</table>
reason for not using, all other standard of care therapies as defined per recognized guidelines

- Member’s height and weight are provided
- Dosing will be calculated using ideal body weight (IBW), unless ONE of the following:
  - If the member’s actual weight is less than their IBW, then dosing will be calculated using their actual weight
  - If the member’s body mass index (BMI) is ≥30 kg/m² OR if their actual weight is greater than 20% of their IBW, then dosing will be calculated using adjusted body weight (adjBW)

**Primary Immunodeficiency*: 

- Patient’s IgG level is provided and below normal for requested indication
- Clinically significant deficiency of humoral immunity as evidenced by ONE of the following:
  - Inability to produce an adequate immunologic response to specific antigens.
  - History of recurrent infections despite prophylactic antibiotics
- Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
- If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
- If criteria is met, approve for 6 months.

*Primary Immunodeficiency includes, but is not limited to, the following: Congenital agammaglobulinemia, hypogammaglobulinemia (Common Variable Immunodeficiency, CVID), severe combined immunodeficiency (SCID), Wiskott-Aldrich syndrome, X-linked agammaglobulinemia or Bruton’s agammaglobulinemia, hypergammaglobulinemia, X-linked hyper IgM syndrome

**Idiopathic Thrombocytopenic Purpura, acute and chronic**: 

- **Acute:**
  - Patient has active bleeding, requires an urgent invasive procedure, is deferring splenectomy, has platelet counts < 20,000/ul and is at risk for intracerebral hemorrhage or has life threatening bleeding, or has an inadequate increase in platelets from
corticosteroids or is unable to tolerate corticosteroids
  o Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days
  • **Chronic:**
    o Duration of illness is greater than 12 months
    o Member has documented trial and failure of corticosteroids and splenectomy, or has a documented medical reason why they are not able to use corticosteroids or member is at high risk for post-splenectomy sepsis.
    o Dose does not exceed 1g/kg daily for up to 2 days, or 400mg/kg daily for 5 days
  • If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C
  • If criteria is met, approve for up to 5 days.

**Kawasaki disease:**
  • Immunoglobulin is being given with high dose aspirin unless contraindicated
  • Requested dose does not exceed a single 2g/kg dose
  • If criteria is met, approve for 1 dose

**Chronic B-cell lymphocytic leukemia:**
  • The patient has had recurrent infections requiring IV antibiotics or hospitalization and has a serum IgG of <500 mg/dL
  • Dose does not exceed 500mg/kg every 3-4 weeks
  • If criteria is met, approve for 3 months.

**Bone marrow transplantation:**
  • The patient has bacteremia or recurrent sinopulmonary infections and their IgG level is < 400mg/dL
  • Dose does not exceed 500mg/kg/wk for the first 100 days post- transplant
  • Dose does not exceed 500 mg/kg every 3-4 weeks 100 days after transplant
  • If criteria is met, approve for 3 months.

**Pediatric HIV:**
  • Patient is < 13 years of age
• Either patient’s IgG level is < 400mg/dL or
• If patient’s IgG level is ≥ 400 mg/dL than significant deficiency of humoral immunity as evidenced by ONE of the following:
  o Inability to produce an adequate immunologic response to specific antigens.
  o History of recurrent bacterial infections despite prophylactic antibiotics
• Dose does not exceed 400mg/kg/dose every 14 days

• If criteria is met, approve for 3 months.

**Multifocal motor neuropathy (MMN):**

• Duration of symptoms has been at least 1 month with disability.
• Nerve conduction studies were completed to rule out other possible conditions, and confirms the diagnosis of MMN.
• Dose does not exceed 2g/kg/month administered over 2 to 5 days.

• If criteria is met, approve for up to 5 days for 3 months.

**Chronic inflammatory demyelinating polyneuropathy (CIDP):**

• Duration of symptoms has been at least 2 months with disability.
• Nerve conduction studies or a nerve biopsy were completed in order to rule out other possible conditions, and confirms the diagnosis of CIDP.
• Patient has tried and failed, or has a documented medical reason for not using, corticosteroids.
  o If the patient has severe and fulminant CIDP a trial of corticosteroids is not required
• Dose is consistent with FDA approved package labeling, nationally recognized compendia, or peer-reviewed literature
• If the request is for any medication other than Gamunex-C, the member has tried and failed, or has a documented medical reason for not using, Gamunex-C

• If criteria is met, approve for up to 5 days for 3 months

**Guillain-Barre syndrome:**
- Patient has severe disease with the inability to walk without aid
- Onset of symptoms within the last 4 weeks
- Dose does not exceed 2g/kg administered over 2-5 days

- If criteria is met, approve for up to 5 days.

**Myasthenia Gravis:**

- **Acute:**
  - Patient has an acute myasthenic exacerbation (i.e. acute episode of respiratory muscle weakness, difficulty swallowing, etc.) or is in preparation for thymoma surgery to prevent myasthenic exacerbation
  - Dose does not exceed 2 g/kg administered over 2-5 days
  - If criteria is met, approve for up to 5 days

- **Chronic:**
  - Diagnosis of refractory generalized myasthenia gravis
  - Patient has tried and failed, or has a documented medical reason for not using 2 or more immunosuppressive therapies (i.e. corticosteroids, azathioprine, cyclosporine, mycophenolate mofetil)
  - Dose does not exceed 2 g/kg/month administered over 2-5 days
  - If criteria is met, approve for 3 months

**Dermatomyositis (DM):**

- One of the following:
  - Bohan and Peter score of 3 (i.e. definite DM)
  - Bohan and Peter score of 2 (i.e. probable DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)
  - Diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM) AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)

- Attestation that patient has been screened for malignancy

- For a diagnosis of DM, one of the following:
  - Member has tried and failed, or has a documented medical reason for not using both of the following:
    - methotrexate (MTX) OR azathioprine
    - rituximab.
  - Member has severe, life-threatening weakness or dysphagia
• For a diagnosis of cutaneous DM (i.e. amyopathic DM, hypomyopathic DM):
  o Member has tried and failed, or has a documented medical reason for not using all of the following: MTX and mycophenolate mofetil.
• Dose does not exceed 2 g/kg administered over 2-5 days every 4 weeks.
• If criteria is met, approve for up to 3 months.

If criteria is met, the request will be approved for the duration listed above. If the criteria is not met, the request is referred to a Medical Director/Clinical reviewer for medical necessity review.

**Medical Director/Clinical Reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary**
<table>
<thead>
<tr>
<th><strong>Field Name</strong></th>
<th><strong>Field Description</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Increlex</td>
</tr>
<tr>
<td>Drugs</td>
<td>Increlex (mecasermin [recombinant human insulin-like growth factor-1])</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>≥ 2 years to &lt; 18 years</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with an Endocrinologist or specialist in the treatment of pediatric growth disorders</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the conditions are met, the request will be approved for 12 months. If all of the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</td>
</tr>
</tbody>
</table>
| Other Criteria | **Initial Authorization**  
  - Member has a diagnosis of one of the following  
    - Growth hormone (GH) gene deletion with the development of neutralizing antibodies to GH  
    - Severe primary insulin-like growth factor-1 (IGF-1) deficiency as defined as:  
      - Height and basal IGF-1 standard deviation scores ≤ -3.0  
      - Normal or elevated GH levels  
  - Member does not have a closed epiphyses  
  - Member does not have known or suspected malignancies  
  - Request is for an FDA-approved dose |
| | **Reauthorization**  
  - Growth velocity must be ≥ 2 cm in the past year  
  - Member does not have a closed epiphyses  
  - Member does not have known or suspected malignancies  
  - Request is for an FDA-approved dose |
<p>| Revision/Review Date | 7/2022 |
| | <strong>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</strong> |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Insulin Pumps</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Omnipod Dash Intro Kit, Omnipod Dash Pods, Omnipod 5 G6 Intro Kit, Omnipod 5 G6 Pods</td>
</tr>
<tr>
<td><strong>This policy does not apply to pumps reviewed and/or covered by the Medical Benefit including, but not limited to V-Go 24-hour disposable system and t:slim X2, and continuous glucose monitor/insulin pumps such as MiniMed. Requests for these products are referred to the plan’s Utilization Management team for review.</strong></td>
<td></td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>None</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>None</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with an endocrinologist, a certified diabetes care and education specialist (CDCES), or an obstetrician/gynecologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the request will be approved for 12 months. If the criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization</strong></td>
</tr>
<tr>
<td></td>
<td>- Diagnosis – diabetes</td>
</tr>
<tr>
<td></td>
<td>- One of the following</td>
</tr>
<tr>
<td></td>
<td>o Type 1 diabetes or other insulin-deficient forms of diabetes (e.g. cystic-fibrosis related diabetes)</td>
</tr>
<tr>
<td></td>
<td>o Treatment with multiple daily doses (≥ 3) of insulin</td>
</tr>
<tr>
<td></td>
<td>o Pregnancy</td>
</tr>
<tr>
<td></td>
<td>o Continuation of therapy for patient new to plan</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization</strong></td>
</tr>
<tr>
<td></td>
<td>- One of the following:</td>
</tr>
<tr>
<td></td>
<td>o Type 1 diabetes or other insulin-deficient form of diabetes</td>
</tr>
<tr>
<td></td>
<td>o Continued use of multiple daily injections (≥ 3) of insulin</td>
</tr>
<tr>
<td></td>
<td>o Initial approval was based on continuation of therapy for patient new to plan.</td>
</tr>
<tr>
<td></td>
<td>- There are no new safety signals relating to the use or improper...</td>
</tr>
</tbody>
</table>
Continuation of therapy based on a diagnosis of pregnancy alone is not eligible for reauthorization.

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Adrenal Enzyme Inhibitors for Cushing’s Disease</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Isturisa (osilodrostat)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Member must be ≥ 18 years of age</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by, or in consultation with, an endocrinologist or other specialist in the treatment of metabolic disorders</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td><strong>Initial Authorization:</strong> If the criteria are met, the request will be approved for a 6-month duration.</td>
</tr>
<tr>
<td></td>
<td>Reauthorization: If the criteria are met, the request will be approved for a 12-month duration.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Member has confirmed diagnosis of Cushing’s Disease</td>
</tr>
<tr>
<td></td>
<td>• Pituitary surgery is not an option or has not been curative</td>
</tr>
<tr>
<td></td>
<td>• Provider attests baseline electrocardiogram (ECG) has been obtained and hypokalemia and/or hypomagnesemia has been corrected prior to initiating therapy if present</td>
</tr>
<tr>
<td></td>
<td>• The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia or peer-reviewed literature</td>
</tr>
<tr>
<td></td>
<td>• Documented baseline urinary free cortisol (UFC) test ≥ 1.3 upper limit of normal (ULN)</td>
</tr>
<tr>
<td></td>
<td>• UFC Normal Range = 3.5-45 mcg/24 hrs (9.66-124.2 nmol/24 hrs)</td>
</tr>
<tr>
<td></td>
<td>• Member has had a documented trial and failure of one of the following:</td>
</tr>
<tr>
<td></td>
<td>• ketoconazole</td>
</tr>
<tr>
<td></td>
<td>• Metopirone (metyrapone)</td>
</tr>
<tr>
<td></td>
<td>• Lysodren (mitotane)</td>
</tr>
<tr>
<td></td>
<td>• cabergoline</td>
</tr>
<tr>
<td></td>
<td>• Signifor/Signifor LAR (pasireotide)</td>
</tr>
<tr>
<td></td>
<td>• etomidate</td>
</tr>
<tr>
<td></td>
<td><strong>OR</strong></td>
</tr>
<tr>
<td></td>
<td>Member has a documented medical reason (e.g, contraindication, intolerance, hypersensitivity) as to why these medications cannot be used</td>
</tr>
</tbody>
</table>
**Reauthorization:**

- Member has responded to therapy as defined by a documented urinary free cortisol (UFC) test ≤ the upper limit of normal (ULN)
- The medication is being prescribed at a dose that is consistent with FDA-approved package labeling, nationally recognized compendia

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th>Prior Authorization Group Description</th>
<th>Jesduvroq (daprodustat)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Diagnosis of uncontrolled hypertension Concomitant use of strong CYP2C8 inhibitors (e.g., gemfibrozil)</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Diagnosis of uncontrolled hypertension Concomitant use of strong CYP2C8 inhibitors (e.g., gemfibrozil)</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Member must be at least 18 years of age</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a hematologist or nephrologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all conditions are met, the request will be approved with a 6 month duration.</td>
</tr>
</tbody>
</table>
| Other Criteria                      | **Initial Authorization:**  
  - Member has a diagnosis of chronic kidney disease (CKD) and has been undergoing dialysis for at least four months  
  - Member has a documented hemoglobin between 8.0 and 11.5 g/dL  
  - Member has documentation of trial and failure, intolerance, contraindication, or inability to use erythropoietin stimulating agents (ESA)  
  - Documentation of the current ESA product (e.g., Procrit, Aranesp, etc.) and dose.  
  - The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:  
    - Serum ferritin level (> 100ng/mL)  
    - Transferrin saturation (TSAT) (> 20%)  
  - Provider attests that member has no history of myocardial infarction, cerebrovascular event, or acute coronary syndrome in the past 3 months  
  - Member will not be receiving concurrent treatment with an ESA  
  - Request is for an FDA-approved dose  
  - All submitted lab results have been drawn within 30 days of the request  
  
**Reauthorization:**  
- All submitted lab results have been drawn within 30 days of the reauthorization request.  
- Member has a documented increase in hemoglobin from baseline  
- The following lab results must be submitted and demonstrate normal values, otherwise, the member MUST be receiving, or is beginning therapy, to correct the deficiency:  
  - Serum ferritin level (> 100ng/mL)  
  - Transferrin saturation (TSAT) (> 20%)
| Revision/Review Date: 04/2023 | - Member will not be receiving concurrent treatment with an ESA
- Request is for an FDA-approved dose

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary |
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Ketamine</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Ketamine (Ketalar)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Depression: N/A</td>
</tr>
<tr>
<td></td>
<td>Complex Regional Pain Syndrome (CRPS): pain management specialist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>Initial: 4 weeks</td>
</tr>
<tr>
<td></td>
<td>Continuation of therapy: 6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Depression</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of major depressive disorder (MDD) or treatment-resistant depression (TRD)</td>
</tr>
<tr>
<td></td>
<td>• Documented trial and failure of two preferred oral antidepressants (e.g. SSRIs, SNRIs, TCAs) of at least a minimum effective dose for four (4) weeks or longer OR a medical justification as to why the patient cannot use preferred alternative(s).</td>
</tr>
<tr>
<td></td>
<td><strong>Re-authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documentation was submitted indicating the member has clinically benefited from therapy.</td>
</tr>
<tr>
<td></td>
<td><strong>CRPS</strong></td>
</tr>
<tr>
<td></td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of CRPS (may also be termed reflex sympathetic dystrophy, algodystrophy, causalgia, Sudeck atrophy, transient osteoporosis, and acute atrophy of bone)</td>
</tr>
<tr>
<td></td>
<td>• Patient has tried and failed at least 8 weeks treatment with or continues to receive physical therapy (PT) and/or occupational therapy (OT).</td>
</tr>
<tr>
<td></td>
<td>• Patient has tried and failed at least two of the following:</td>
</tr>
<tr>
<td></td>
<td>o NSAIDs</td>
</tr>
<tr>
<td></td>
<td>o Anticonvulsants (e.g. gabapentin, pregabaline)</td>
</tr>
<tr>
<td></td>
<td>o Antidepressants (e.g. SNRIs, TCAs)</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td></td>
</tr>
<tr>
<td>----------------------</td>
<td>--------------------------------------------------</td>
</tr>
<tr>
<td>4/2023</td>
<td>Bisphosphonate (in the setting of abnormal uptake on bone scan)</td>
</tr>
<tr>
<td></td>
<td>Patient has demonstrated clinical benefit.</td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td>Kuvan</td>
</tr>
<tr>
<td>Drug(s)</td>
<td>sapropterin (Kuvan)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>*Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>None</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>None</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Specialist experienced in treating Phenylketonuria (PKU)</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td><strong>Initial</strong>: If the criterion is met, the request will be approved for a duration of 1 month; if the above conditions are not met, the request will be referred to a clinical reviewer for medical necessity review. <strong>Reauthorization</strong>: If the criteria is met, the request will be approved for a duration of 1 month for patients who require a dose increase to 20 mg/kg/day due to non-responsiveness and for all other patients the request will be approved for a duration of 6 months; if the above conditions are not met, the request will be referred to a clinical reviewer/Medical Director for medical necessity review.</td>
</tr>
</tbody>
</table>
| Other Criteria                   | **INITIAL AUTHORIZATION:**  
- Documentation of a confirmed diagnosis of Phenylketonuria (PKU)  
- Documentation of the patient’s baseline blood Phe level (within 30 days of the request)  
- Documentation or prescriber attestation that the patient is currently utilizing a Phe-restricted diet  
- Documentation of the patient’s current weight.  
- The medication is being prescribed at an FDA approved dosage  

**PA CRITERIA FOR REAUTHORIZATION:**  
*Patients that were dosed at 20mg/kg/day and did not have a decrease in Phe level of at least 30% from baseline, are considered NON RESPONDERS and NO ADDITIONAL TREATMENT will be authorized.*  
- Documentation of the patient’s current weight.  
- Documentation of updated blood Phe level results showing reduction in Phe level from baseline. |
| Last review: 4/2023 | - The medication is being prescribed at an FDA approved dosage.  

**NOTE:** Clinical reviewer/Medical Director must override criteria when, in his/her professional judgment, the requested item is medically necessary. |
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Lamzede</td>
</tr>
<tr>
<td>Group Description</td>
<td>Lamzede (velmanase alfa-tycv)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Covered Uses</td>
<td></td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>“See Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a specialist in the treatment of alpha-mannosidosis or other lysosomal storage disorders</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the request will be approved for 12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of alpha-mannosidosis as confirmed by one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Deficiency in alpha-mannosidase enzyme levels or activity in blood leukocytes</td>
</tr>
<tr>
<td></td>
<td>o DNA testing</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests patient can walk without support</td>
</tr>
<tr>
<td></td>
<td>• Patient’s weight</td>
</tr>
<tr>
<td></td>
<td>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient has demonstrated a clinical response (i.e., reduction in serum oligosaccharide concentrations, stabilization or improvement in 3-minute stair climbing test [3MSCT], 6-minute walking test [6-MWT], forced vital capacity [FVC], etc.)</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests that medication will only be used to treat non-central nervous system manifestations of alpha-mannosidosis</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attests patient can walk without support</td>
</tr>
<tr>
<td></td>
<td>• Patient’s weight</td>
</tr>
<tr>
<td></td>
<td>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>4/2023</td>
</tr>
<tr>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
<td></td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
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<tr>
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</tr>
<tr>
<td>Prior Authorization Group Description</td>
<td>linezolid (Zyvox)</td>
</tr>
<tr>
<td>Drugs</td>
<td>linezolid (Zyvox)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved with up to a 1 month duration.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>The Patient meets one of the two following criteria:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documented history of treatment with linezolid IV (continuation of therapy, IV to PO conversion).</td>
</tr>
<tr>
<td></td>
<td>• Documented trial and failure, or intolerance, to 1 preferred antibiotic to which the organism is susceptible.</td>
</tr>
<tr>
<td></td>
<td><strong>AND</strong></td>
</tr>
<tr>
<td></td>
<td>• Requests for linezolid oral suspension require a documented trial and failure of linezolid oral tablets or a medical reason (e.g. intolerance, hypersensitivity, contraindication) why linezolid oral tablets cannot be used.</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>4/2023</td>
</tr>
<tr>
<td></td>
<td><strong>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</strong></td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>-------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>Atovaquone Suspension</td>
</tr>
<tr>
<td>Group Description</td>
<td>Atovaquone (Mepron) suspension</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Information</td>
<td></td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved with up to a 6 month duration.</td>
</tr>
</tbody>
</table>
| Other Criteria          | **Treatment/Prevention of *Pneumocystis jirovecii* pneumonia**  
                          • Diagnosis of mild to moderate *Pneumocystis jirovecii* pneumonia (PCP) or diagnosis with the need to prevent PCP infection  
                          • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX).  
                          • Documented trial and failure with therapeutic doses or intolerance to dapsone.  
                          
                          **Treatment/Prevention of *Toxoplasma gondii* encephalitis in patients with HIV:**  
                          • Diagnosis of *Toxoplasma gondii* encephalitis or documentation of supporting diagnosis for prophylaxis  
                          • Documented trial and failure with therapeutic doses or intolerance to trimethoprim- sulfamethoxazole (TMP-SMX).  
                          
                          **Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.** |
<p>| Revision/Review Date    | 4/2023                                                                                                                                              |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Mucopolysaccharidosis II (Hunter Syndrome) Agents</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td><strong>Elaprase (idursulfase)</strong></td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>“See Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Patient is ≥ 16 months of age</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a specialist in genetics or metabolic disorders</td>
</tr>
</tbody>
</table>
| Coverage Duration          | Initial Authorization: 6 months  
Reauthorization: 12 months                                                                                                                                                                                                                  |
| Other Criteria             | **Initial Authorization**  
- Diagnosis of Mucopolysaccharidosis II as confirmed by one of the following:  
  o Enzyme assay demonstrating a deficiency of iduronate 2-sulfatase activity  
  o Genetic testing  
- Patient’s weight  
- Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines  
**Reauthorization**  
- Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 6-minute walk test [6-MWT], forced vital capacity [FVC], urinary glycosaminoglycan (GAG) levels, liver volume, spleen volume, etc.)  
- Patient’s weight  
- Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines  
Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.  
Revision/Review Date 7/2022
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Multaq</td>
</tr>
<tr>
<td>Drugs</td>
<td>Multaq (dronedarone)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Pregnancy</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Request must be from a cardiologist or electrophysiologist.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved with up to a 12 month duration.</td>
</tr>
</tbody>
</table>
| Other Criteria                   | • Diagnosis of paroxysmal or persistent arterial fibrillation (AF) or atrial flutter (AFL) with a recent episode.  
                            |   • Must not have NYHA Class IV heart failure or symptomatic heart failure with recent decompensation requiring hospitalization or referral to a specialized heart failure clinic  
                            |   • Must have AF that can be cardioverted into normal sinus rhythm, or is currently in sinus rhythm  
<pre><code>                        |   • Prescriber attests women of childbearing potential have been counseled regarding appropriate contraceptives |
</code></pre>
<p>| Revision/Review Date 4/2023      | Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary. |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Oralair</strong> (sweet vernal/orchard/rye/timothy/Kentucky blue grass mixed pollen</td>
</tr>
<tr>
<td>Group Description</td>
<td>allergenic extract)</td>
</tr>
<tr>
<td>Drugs</td>
<td><strong>Oralair</strong> (sweet vernal/orchard/rye/timothy/Kentucky blue grass mixed pollen</td>
</tr>
<tr>
<td></td>
<td>allergenic extract)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food</td>
</tr>
<tr>
<td></td>
<td>and Drug Administration (FDA), Micromedex, American Hospital Formulary Service</td>
</tr>
<tr>
<td></td>
<td>(AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional</td>
</tr>
<tr>
<td></td>
<td>(USP DI), the Drug Package Insert (PPI), or disease state specific standard of care</td>
</tr>
<tr>
<td></td>
<td>guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Information</td>
<td></td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>According to Package Insert</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber is an allergist or immunologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the conditions are met, the request will be approved for a 12 month</td>
</tr>
<tr>
<td></td>
<td>duration.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>For all requests:</td>
</tr>
<tr>
<td></td>
<td>• Requested allergenic extract is being used to treat allergic rhinitis with</td>
</tr>
<tr>
<td></td>
<td>or without conjunctivitis</td>
</tr>
<tr>
<td></td>
<td>• Member has had a document trial an failure of, or intolerance to, an intranasal</td>
</tr>
<tr>
<td></td>
<td>corticosteroid (e.g. fluticasone) used in combination with at least one of the</td>
</tr>
<tr>
<td></td>
<td>following:</td>
</tr>
<tr>
<td></td>
<td>o Oral antihistamine (e.g. cetirizine)</td>
</tr>
<tr>
<td></td>
<td>o Intranasal antihistamine (e.g. azelastine)</td>
</tr>
<tr>
<td></td>
<td>o Oral leukotriene receptor antagonist (montelukast)</td>
</tr>
<tr>
<td></td>
<td>• Patient has been prescribed (as demonstrated by pharmacy claims or documentation)</td>
</tr>
<tr>
<td></td>
<td>injectable epinephrine</td>
</tr>
<tr>
<td></td>
<td><strong>Oralair:</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis has been confirmed by positive skin, or in vitro, testing to Sweet</td>
</tr>
<tr>
<td></td>
<td>Vernal, Orchard, Rye, Timothy, Kentucky Blue Grass, or cross reactive, pollen</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization:</strong></td>
</tr>
<tr>
<td></td>
<td>For all requests:</td>
</tr>
<tr>
<td></td>
<td>• Member has experienced a reduction in symptoms associated with allergic rhinitis</td>
</tr>
<tr>
<td></td>
<td>**Medical Director/clinical reviewer must override criteria when, in his/her</td>
</tr>
<tr>
<td></td>
<td>professional judgement, the requested item is medically necessary.</td>
</tr>
</tbody>
</table>

Revision/Review Date 10/2022
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Oxlumo (lumasiran)</td>
</tr>
<tr>
<td>Group Description</td>
<td>Oxlumo (lumasiran)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a nephrologist, urologist, hepatologist, endocrinologist or consultation with one of these specialists</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization</strong></td>
</tr>
</tbody>
</table>
|                     | • Diagnosis of primary hyperoxaluria type 1 (PH1) confirmed by one of the following:  
|                     |   o Genetic testing confirming at least one mutation at the AGXT gene  
|                     |   o Liver biopsy demonstrating absent or significantly reduced AGT activity  
|                     | • Metabolic testing demonstrating one of the following:  
|                     |   o Increased urinary oxalate excretion ($\geq 0.5$ mmol/1.73 m³ per day[45 mg/1.73 m³ per day])  
|                     |   o Increased urinary oxalate:creatinine ratio relative to normative values for age  
|                     |   o Increased plasma oxalate level ($\geq 20$ μmol/L)  
|                     | • Member is concurrently using pyridoxine or has tried and failed previous pyridoxine therapy for at least 3 months, or has a medical reason for not using pyridoxine  
|                     | • Member has no history of liver transplant  
|                     | • Medication is prescribed at an FDA approved dose |
| Reauthorization     |                                    |
| Revision/Review Date 1/2023 | • Members previously using pyridoxine will continue to use pyridoxine, or have a medical reason for not using pyridoxine  
• Documentation has been provided that demonstrates a clinical benefit (e.g. symptomatic improvement, reduction in urinary or plasma oxalate levels from baseline)  
• Medication is prescribed at an FDA approved dose  

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary. |
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Palynziq</td>
</tr>
<tr>
<td>Drugs</td>
<td>Palynziq (pegvaliase-pqpz)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>None</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>None</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Specialist experienced in the treatment of phenylketonuria (PKU).</td>
</tr>
</tbody>
</table>
| Coverage Duration          | Initial Authorizations: 12 months  
Dose Increases (to 40 mg or 60 mg daily): 16 weeks  
Reauthorization: 12 months                                                                                                                                 |
| Other Criteria             | **INITIAL AUTHORIZATION:**  
- Documentation of a confirmed diagnosis of Phenylketonuria (PKU);  
  **AND**  
- Documentation the member’s blood phenylalanine (Phe) level is greater than 600 micromol/L (include lab results; must be within the past 90 days)  
- Documentation or prescriber attestation that the member has attempted control of PKU through a Phe restricted diet with Phe-free medical products/foods in conjunction with dietician or nutritionist. (Examples include Phenyl-Free [phenylalanine free diet powder], Lopex, Periflex, Phlex-10, PKU 2, PKU 3, XPhe Maxamaid, XPhe Maxamum)  
- Member has previously received sapropterin (Kuvan) and either had an inadequate response, was a non-responder (defined as members who were dosed at 20 mg/kg/day and did not have a decrease in blood Phe level after 1 month), or has a documented medical reason why sapropterin (Kuvan) cannot be used  
- The medication is being prescribed at a dose no greater than the FDA approved maximum initial dose of 20 mg SQ once daily.  
**DOSE INCREASES:**  
- Documentation of recent blood Phe level results (within the past 90 days).  
- Confirmation Phe control has not been achieved after adequate timeframe on the current dosing regimen:
For requests for a dose of 40 mg per day, the patient has been on 20 mg once daily continuously for at least 24 weeks and has not achieved adequate control

For requests for a dose of 60 mg per day, the patient has been on 40 mg once daily continuously for at least 16 weeks and has not achieved adequate control

- The medication is being prescribed at an FDA approved dose (maximum of 60 mg once daily).

**REAUTHORIZATION:**

- Documentation of recent blood Phe level results (within the previous 90 days); **AND**
- The medication is being prescribed at an FDA approved dose; **AND**
- Member has achieved a reduction in blood phenylalanine concentration from pre-treatment baseline.

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Peanut Allergy Immunotherapy Agents (FDA Approved)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Palforzia [Peanut (Arachis hypogaea) Allergen Powder-dnfp] capsule/sachet</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Initiation: Patient is age 4-17 years. Up dosing and maintenance: Patient is age ≥ 4 years</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber is a specialist in the area of allergy/immunology</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong>&lt;br&gt;Palforzia is approved when all of the following criteria are met:&lt;br&gt;• Patient has a confirmed diagnosis of peanut allergy&lt;br&gt;• For patients starting initial dose escalation (new to therapy)&lt;br&gt;  o Patient has not had severe or life-threatening anaphylaxis within the previous 60 days&lt;br&gt;• Patient will follow a peanut-avoidant diet&lt;br&gt;• Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine&lt;br&gt;• No history of eosinophilic esophagitis or other eosinophilic gastrointestinal disease&lt;br&gt;• Patient does not have uncontrolled asthma&lt;br&gt;&lt;br&gt;<strong>Criteria for Re-Authorization:</strong>&lt;br&gt;Palforzia is approved for re-authorization when all of the following criteria are met&lt;br&gt;• Patient will follow a peanut-avoidant diet&lt;br&gt;• Patient is able to tolerate at least the 3 mg dose daily&lt;br&gt;• Patient is able to comply with the daily dosing requirements&lt;br&gt;• Patient does not have recurrent asthma exacerbations or persistent loss of asthma control&lt;br&gt;• Patient has been prescribed and has acquired (as demonstrated by pharmacy claims or documentation) injectable epinephrine</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
</tr>
<tr>
<td>----------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>4/2023</td>
<td></td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>----------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td>Adrenergic, alpha-receptor-blocking agent</td>
</tr>
<tr>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>Drug(s)</td>
<td>Phenoxybenzamine (Dibenzyline)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with an endocrinologist or specialist in the management of pheochromocytoma.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the conditions are met, the request will be approved for up to a 14-day duration for perioperative management or up to a 6 month duration for non-surgical initial requests. For continuation of therapy, the request will be approved for 12 months. Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of pheochromocytoma</td>
</tr>
<tr>
<td></td>
<td>• Documented use for either perioperative management or long term use when surgery is contraindicated</td>
</tr>
<tr>
<td></td>
<td>• Documented trial and failure, intolerance, or contraindication to doxazosin</td>
</tr>
<tr>
<td></td>
<td>• Medication is prescribed at an FDA approved dose</td>
</tr>
<tr>
<td></td>
<td><strong>Re-Authorization</strong></td>
</tr>
<tr>
<td></td>
<td>• Documented long term use when surgery is contraindicated</td>
</tr>
<tr>
<td></td>
<td>• Documentation or provider attestation that demonstrates a clinical benefit</td>
</tr>
<tr>
<td></td>
<td>• Medication is prescribed at an FDA approved dose</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>1/2023</td>
</tr>
<tr>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
<td></td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>-------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td><strong>Dendritic Cell Tumor Peptide Immunotherapy</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td><strong>Provenge (sipuleucel-T)</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Small cell/neuroendocrine prostate cancer</td>
</tr>
<tr>
<td>Required Medical</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Information</td>
<td></td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be an oncologist or urologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>3 doses per lifetime</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>- Metastatic castrate resistant (hormone-refractory) prostate cancer (mCRPC) (consistent with medical chart history)</td>
</tr>
<tr>
<td></td>
<td>o Evidenced by soft tissue and/or bony metastases</td>
</tr>
<tr>
<td></td>
<td>o Patient does NOT have</td>
</tr>
<tr>
<td></td>
<td>▪ M0CRPC (defined as CRPC whose only evidence of disseminated disease is an elevated serum PSA) is not authorized</td>
</tr>
<tr>
<td></td>
<td>▪ Visceral metastases (e.g. liver, lung, adrenal, peritoneal, brain)</td>
</tr>
<tr>
<td></td>
<td>- Patient is not currently being treated with systemic immunosuppressants (e.g. chemotherapy, corticosteroids) or, if the patient is being treated with immunosuppressants, the prescriber has provided a valid medical reason for combination therapy</td>
</tr>
<tr>
<td></td>
<td>- Eastern Cooperative Oncology Group (ECOG) score 0-1</td>
</tr>
<tr>
<td></td>
<td>- Serum testosterone &lt;50 ng/dL (e.g. castration levels of testosterone)</td>
</tr>
<tr>
<td></td>
<td>- Predicted survival of at least six months</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization:</strong></td>
</tr>
<tr>
<td></td>
<td>- Treatment exceeding 3 doses per lifetime will not be authorized</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>5/2022</td>
</tr>
<tr>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
<td></td>
</tr>
<tr>
<td>Prior Authorization Group Description</td>
<td>Dojolvi</td>
</tr>
<tr>
<td>--------------------------------------</td>
<td>---------</td>
</tr>
<tr>
<td>Drugs</td>
<td>Dojolvi (triheptanoin)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber is a specialist in the treatment of the indicated condition</td>
</tr>
</tbody>
</table>
| Coverage Duration | Initial: 6 months  
Renewal: 12 months |
| Other Criteria | **Initial Authorization:**  
- Member has a molecularly confirmed diagnosis of a long-chain fatty acid oxidation disorder (LC-FAOD)  
- Documentation of at least two of the following:  
  - Disease specific elevation of acylcarnitines on a newborn blood spot or in plasma  
  - Low enzyme activity in cultured fibroblasts  
  - One or more known pathogenic mutations in either the CPT2, ACADVL, HADHA, or HADHB gene  
- Member will not be receiving any other medium-chain triglyceride products while taking Dojolvi  
- Documentation of member’s daily caloric intake (DCI)  
- Dose is within FDA-indicated limits and does not exceed 35% of DCI  

**Re-Authorization:**  
- Documentation submitted indicating the member has experienced a clinical benefit (e.g. increased left ventricular ejection fraction, reduced left ventricular wall mass, reduced maximum heart rate, decreased incidence of rhabdomyolysis)  
- Documentation of member’s DCI  
- Dose is within FDA-indicated limits and does not exceed 35% of DCI  

<p>| Revision/Review Date: 1/2023 | Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary. |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td>Step 1: Rituximab (Rituxan, Truxima, Riabni, Ruxience), Step 2: Enspryng (satralizumab-mwge) Step 3: Uplizna (inebilizumab-cdon) Step 3: Soliris (eculizumab)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>For Enspryng, Uplizna, Soliris: Anti-aquaporin-4 (AQP4) antibody negative neuromyelitis optica spectrum disorder (NMOSD)</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td><strong>See “Other Criteria”</strong></td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>According to package insert</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a specialist who is experienced in the treatment of NMOSD (such as immunologist, neurologist or hematologist)</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the conditions are met, requests will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>For rituximab (Rituxan, Truxima, Riabni, or Ruxience):</td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of NMOSD</td>
</tr>
<tr>
<td></td>
<td>• Documentation indicating that the patient has been screened for HBV (hepatitis B virus) prior to initiation of treatment</td>
</tr>
<tr>
<td></td>
<td>• Dosing is supported by compendia or standard of care guidelines</td>
</tr>
<tr>
<td></td>
<td>• If the request is for any medication other than Ruxience (rituximab-pvvr) or Riabni (rituximab-arrx), there is a documented trial and failure of Ruxience or Riabni, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) they cannot be used</td>
</tr>
<tr>
<td></td>
<td>For Ensplayng:</td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD</td>
</tr>
<tr>
<td></td>
<td>• Provider attests to completion of the following assessments prior to the first dose of Enspryng as outlined in the prescribing information:</td>
</tr>
<tr>
<td></td>
<td>o Hepatitis B virus screening</td>
</tr>
<tr>
<td></td>
<td>o Tuberculosis screening</td>
</tr>
</tbody>
</table>
Liver transaminase screening

- Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Enspryng therapy

- Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil, or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used

- Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Exceptions:
Requests for drugs in step 2 (Enspryng, Uplizna) may be approved without a trial and failure of rituximab (Rituxan, Truxima, Riabni, Ruxience), azathioprine, or mycophenolate if the member has been using Soliris

For Uplizna:
- Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD
- Provider attests to completion of appropriate assessments prior to the first dose of Uplizna as outlined in the prescribing information:
  - Hepatitis B virus screening
  - Quantitative serum immunoglobulins
  - Tuberculosis screening
  - Patient has not received live or attenuated-live virus vaccines within 4 weeks before the start of Uplizna therapy
- Documented trial and failure of rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil or medical reason why (e.g., intolerance, hypersensitivity, contraindication) they cannot be used
- Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines

Exceptions:
Requests for drugs in step 2 (Enspryng, Uplizna) may be approved without a trial and failure of rituximab (Rituxan, Truxima, Riabni, Ruxience), azathioprine, or mycophenolate if the member has been using Soliris

For Soliris:
- Member has a diagnosis of anti-aquaporin-4 (AQP4) antibody positive NMOSD
| Revision/Review Date 10/222 | • Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed  
• Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks if the meningococcal vaccine is administered < 2 weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis.  
• Documented trial and failure of, or medical reason why (e.g. intolerance, hypersensitivity, contraindication) why the following cannot be used (one from each bullet below):  
  o Rituximab (Rituxan, Truxima, Riabni, or Ruxience), azathioprine, or mycophenolate mofetil  
  o Enspryng  
  o Uplizna  
• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines  

**Reauthorization:**  
• Documentation that the prescriber has evaluated the member and recommends continuation of therapy (clinical benefit)  
• Request is for an FDA approved/medically accepted dose  

  Physician/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.  |
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group</td>
<td>Mucopolysaccharidosis VI (Maroteaux-Lamy Syndrome) Agents</td>
</tr>
<tr>
<td>Description</td>
<td>Drugs</td>
</tr>
<tr>
<td>Naglazyme (galsulfase)</td>
<td>Covered Uses</td>
</tr>
<tr>
<td>Medically accepted indications</td>
<td>N/A</td>
</tr>
<tr>
<td>are defined using the following</td>
<td>Required Medical</td>
</tr>
<tr>
<td>sources: the Food and Drug</td>
<td>Information</td>
</tr>
<tr>
<td>Administration (FDA), Micromedex,</td>
<td>“See Other Criteria”</td>
</tr>
<tr>
<td>American Hospital Formulary</td>
<td>Age Restrictions</td>
</tr>
<tr>
<td>Service (AHFS), United States</td>
<td>N/A</td>
</tr>
<tr>
<td>Pharmacopeia Drug Information</td>
<td>Prescriber</td>
</tr>
<tr>
<td>for the Healthcare Professional</td>
<td>Restrictions</td>
</tr>
<tr>
<td>(USP DI), the Drug Package</td>
<td>N/A</td>
</tr>
<tr>
<td>Insert (PPI), or disease state</td>
<td>Coverage Duration</td>
</tr>
<tr>
<td>specific standard of care</td>
<td>Initial: 6 months</td>
</tr>
<tr>
<td>guidelines.</td>
<td>Renewal: 12 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>Initial Authorization</td>
</tr>
<tr>
<td>• Diagnosis of Mucopolysaccharidosis VI as confirmed by one of the following:</td>
<td></td>
</tr>
<tr>
<td>o Enzyme assay demonstrating a deficiency in N-acetylgalactosamine 4-sulfatase (arylsulfatase B) enzyme activity</td>
<td></td>
</tr>
<tr>
<td>o DNA testing</td>
<td>Reauthorization</td>
</tr>
<tr>
<td>• Patient’s weight</td>
<td>Patient has demonstrated a beneficial response (i.e., stabilization or improvement in 12-minute walk test [12-MWT], 3-minute stair climb test, urinary glycosaminoglycan (GAG) levels, etc.)</td>
</tr>
<tr>
<td>• Dosing is consistent with FDA-approved labeling or is supported by compendia or standard of care guidelines</td>
<td></td>
</tr>
<tr>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
<td></td>
</tr>
</tbody>
</table>

Revision/Review Date: 1/2023
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Pyruvate Kinase Activators</td>
</tr>
<tr>
<td>Drugs</td>
<td>Pyrukynd (mitapivat)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Age ≥18 years</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a hematologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 6-month duration for renewal requests. **If the conditions are not met: may approve up to 14 days of a Pyrukynd Taper Pack to allow for discontinuation tapering If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
</tbody>
</table>

**Other Criteria**

**Initial Authorization:**
- The prescribed dose is within FDA approved dosing guidelines
- Diagnosis of hemolytic anemia with pyruvate kinase deficiency (PKD)
- Documentation of at least two variant alleles in the pyruvate kinase liver and red blood cell (PKLR) gene, of which at least one is a missense variant
- Documentation that the member is **not** homozygous for the R479H variant
- Documentation that the member **does not have** two non-missense variants of the PKLR gene, without the presence of another missense variant in the PKLR gene
- Documentation of ONE of the following:
  - The member does not regularly require blood transfusions (defined as requiring less than or equal to 3 red blood cell (RBC) transfusions in the past 52 weeks and no transfusions in the past 3 months) AND hemoglobin (Hb) level ≤ 10 g/dL
  - The member has required more than or equal to 6 RBC transfusions in the past 12 months
<table>
<thead>
<tr>
<th>Revision/Review Date: 7/2022</th>
</tr>
</thead>
</table>

- Documentation of the number of transfusions and the number of red blood cell (RBC) units transfused
- Prescriber attests that the member does not have moderate or severe hepatic dysfunction
- Prescriber attests that the member has not had a splenectomy in the past 12 months
- Prescriber attests that the member does not have a history of a prior bone marrow or stem cell transplant
- The member is not concurrently using hematopoietic-stimulating agents (e.g. Procrit or Retacrit)
- Prescriber attests the member is taking at least 0.8mg of folic acid daily

**Reauthorization:**
- The prescribed dose is within FDA approved dosing guidelines
- For the first reauthorization, documentation of benefit: increase in Hb ≥1.5 g/dL over baseline OR a reduction in transfusions, defined as ≥33% reduction in the number of red blood cell (RBC) units transfused over baseline
- For subsequent reauthorizations: documentation of benefit: stabilization in Hb levels OR a sustained reduction in transfusions
- If the reauthorization criteria are not met, may authorize up to 14 days of a Pyrukynd Taper Pack to allow for tapering. To reduce the risk of acute hemolysis, abrupt discontinuation of Pyrukynd should be avoided.

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th>Prior Authorization Group Description</th>
<th>Reblozyl (luspatercept-aamt)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Drugs</td>
<td>Reblozyl (luspatercept-aamt) vial for subcutaneous injection</td>
</tr>
</tbody>
</table>

| Covered Uses | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria | Members are excluded if they have hemoglobin S/beta-thalassemia, isolated alpha-thalassemia, or myelodysplastic syndrome without ring sideroblasts. |
| Required Medical Information | See “other criteria” |

| Age Restrictions | Member must be 18 years of age or older |
| Prescriber Restrictions | Prescriber must be a hematologist or oncologist |

| Coverage Duration | Initial requests will be approved for 3 months. Reauthorization requests will be approved for 6 months. |

<p>| Other Criteria | <strong>Criteria for initial approval:</strong> |
|               | • Requested dose is appropriate per labeling |
|               | • The member’s weight has been provided with the request |
|               | • The member’s most recent hemoglobin level (within the last month) has been provided with the request |
|               | • Diagnosis appropriate per Covered Uses |
|               | • For requests for anemia due to beta thalassemia, documentation of all of the following is required: |
|               | o Member requires regular RBC transfusions (defined as no transfusion-free period of more than 35 days over the last 6 months) |
|               | • For requests for anemia due to myelodysplastic syndrome, documentation of all of the following is required: |
|               | o Documentation of 5% or greater ring sideroblasts present in bone marrow |
|               | o Myelodysplastic Syndrome Revised International Prognostic Scoring System (IPSS-R) categorization as very low, low, or intermediate risk of progression. |
|               | o Member has tried and failed (or medical justification provided for not using) at least one erythropoiesis stimulating agent (ESA) at a dose equivalent to one of the following regimens: |
|               | ▪ Recombinant human erythropoietin ≥ 40,000 IU/week of for at least 8 doses |
|               | ▪ Darbepoetin ≥ 500 ug every 3 weeks for at least 4 doses OR |
|               | ▪ If erythropoietin &gt; 500 mU/mL, trial of ESA is not |</p>
<table>
<thead>
<tr>
<th>Required</th>
</tr>
</thead>
<tbody>
<tr>
<td>o Member has required transfusion of 2 or more red blood cell (RBC) units within an 8 week period in the last 4 months</td>
</tr>
<tr>
<td>o Hemoglobin less than 10 g/dl</td>
</tr>
</tbody>
</table>

**Reauthorization:**
- For diagnosis of anemia due to beta thalassemia, documentation of the following:
  o Fewer transfusions compared with baseline
  AND
  o A reduction in transfusion requirement of at least 2 red-cell units compared with baseline
- Diagnosis of anemia due to myelodysplastic syndrome: documentation of ONE of the following:
  o Hemoglobin increase of at least 1.5 g/dl from baseline over a period of 3-6 months
  OR
  o Reduction in red blood cell transfusion by at least 4 units over a period of 3-6 month compared with baseline transfusion requirement
- Prescriber states that the member did not experience a Grade 3 or 4 hypersensitivity reaction.

**If the above conditions are not met, the request will be referred to a Medical Director for medical necessity review.**
### Prior Authorization

**Group Description**
Adrenal Enzyme Inhibitors for Cushing’s Syndrome

**Drugs**
Recorlev (levoketoconazole)

**Covered Uses**
Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.

**Exclusion Criteria**
- Patients with a non-endogenous source of hypercortisolism, such as exogenous source of glucocorticoids or therapeutic use of ACTH.
- Patient has a diagnosis of pituitary or adrenal carcinoma

**Required Medical Information**
See “Other Criteria”

**Age Restrictions**
Per FDA approved package insert

**Prescriber Restrictions**
Prescriber must be an endocrinologist or in consultation with an endocrinologist

**Coverage Duration**
If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.

**Other Criteria**

#### Initial Authorization:
- Patient has a diagnosis of endogenous Cushing’s syndrome.
- Patient is not a candidate for surgery, surgery is not an option, or prior surgery has not been curative.
- Documented baseline urinary free cortisol (UFC) test \( \geq 1.5 \) times ULN (within the past 30 days).
- Patient has tried and failed, or has a medical reason for not using, ketoconazole.
- Medication is prescribed at an FDA approved dose.

#### Re-Authorization:
- Documentation or provider attestation of positive clinical response (i.e. decrease in urinary free cortisol from baseline.)
- Medication is prescribed at an FDA approved dose

If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.

**Revision/Review Date:** 4/2023
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Relyvrio (sodium phenylbutyrate and taurursodiol)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Relyvrio (sodium phenylbutyrate and taurursodiol)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>According to package insert</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a neurologist, neuromuscular specialist, or physician specializing in the treatment of amyotrophic lateral sclerosis (ALS)</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all the criteria are met, initial and renewal requests will be approved for 6 months</td>
</tr>
</tbody>
</table>
| Other Criteria                | **Initial Authorization:**  
  • Medication is prescribed at an FDA approved dose  
  • Diagnosis of ALS with onset of symptoms within the previous 18 months  
  • Member is not dependent on invasive ventilation or tracheostomy  
  • Documentation of slow vital capacity (SVC) > 60%  

**Re-Authorization:**  
• Documentation or provider attestation of positive clinical response (such as improvement, stabilization, or slowed decline in the Revised ALS Functional Rating Scale (ALSFRS-R) total score)  
• Member is not dependent on invasive ventilation or tracheostomy  
• Medication is prescribed at an FDA approved dose  

If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review. |
<p>| Review/Revision Date: 1/2023   |                                                                                                                                                                                                              |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group</td>
<td><strong>Treatments for Plasminogen Deficiency Type 1 (PLD1)</strong></td>
</tr>
<tr>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>Ryplazim (human plasma-derived plasminogen)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a hematologist, medical geneticist, or other specialist in the treatment of rare blood or genetic disorders</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 12 weeks. Reauthorization requests will be approved for 12 weeks if the member has not had a documented positive response to therapy and for 12 months if the member has had a documented positive response to therapy.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization</strong></td>
</tr>
<tr>
<td></td>
<td>- Member must have a diagnosis of PLD1 (i.e. hypoplasminogenemia)</td>
</tr>
<tr>
<td></td>
<td>- Member must have a documented history of lesions or other symptoms consistent with the diagnosis (e.g. ligneous conjunctivitis, oral, respiratory, gastrointestinal, urogenital, integumentary, or central nervous system manifestations)</td>
</tr>
<tr>
<td></td>
<td>- Member must have baseline plasminogen activity levels ≤ 45%</td>
</tr>
<tr>
<td></td>
<td>- If the member received plasminogen supplementation with fresh frozen plasma, prescriber attests that a 7-day washout period was performed before obtaining baseline plasminogen activity levels.</td>
</tr>
<tr>
<td></td>
<td>- The request is for an FDA approved dose</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization</strong></td>
</tr>
<tr>
<td></td>
<td>- ONE of the following is true:</td>
</tr>
<tr>
<td></td>
<td>- Member has a documented positive response to therapy (e.g. reduction in number or size of lesions, no new or recurring lesions)</td>
</tr>
<tr>
<td></td>
<td>- Member has not had a documented positive response to therapy and ONE of the following:</td>
</tr>
<tr>
<td></td>
<td>- If confirmed plasminogen activity levels are ≥ 10% above baseline, then appropriate dosing frequency adjustments must be made.</td>
</tr>
<tr>
<td></td>
<td>- If confirmed plasminogen activity levels are &lt; 10% above baseline, then appropriate dosing frequency adjustments must be made.</td>
</tr>
</tbody>
</table>
adjustments must be made AND the prescriber must provide a medical justification as to why therapy should be continued.

- The request is for an FDA approved dose

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
Rituximab

Drugs:
Rituxan (rituximab)
Rituxan Hycela (rituximab/hyaluronidase human, recombinant)
Truxima (rituximab-abbs)
Ruxience (rituximab-pvvr)
Riabni (rituximab-arrx)

RITUXIMAB WILL BE APPROVED IF THE FOLLOWING PRIOR AUTHORIZATION CRITERIA IS MET:

NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD):
- Refer to the “Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents” policy

RHEUMATOID ARTHRITIS:

Initial Authorization
- The medication is being recommended and prescribed by a rheumatologist.
- The patient is an adult (≥18 y/o) and has a documented clinical diagnosis of rheumatoid arthritis.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates and doses) of 3 months or more of therapy with one conventional (non-biologic) DMARD (e.g. methotrexate, leflunomide, sulfasalazine, hydroxychloroquine) or has a documented medical reason (e.g. intolerance, hypersensitivity) for not utilizing any of these therapies to manage their medical condition.
- The patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses) of 2 preferred biologics indicated for rheumatoid arthritis, or has documented medical reason (intolerance, hypersensitivity, etc.) for not taking the preferred therapies to manage their medical condition.
- Documentation indicating that rituximab is being used concurrently with methotrexate.
- Documentation indicating that the patient has been screened for Hepatitis B Virus (HBV) prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the request is for any medication other than Ruxience(rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g.
intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

**Reauthorization**

- The member has been receiving rituximab and documentation is provided that a rheumatologist has reevaluated the member and recommends continuation of therapy.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- At least 16 weeks (4 months) has elapsed since the previous course of rituximab therapy.
- Documentation indicating that rituximab is being used concurrently with methotrexate.
- Rituximab is being prescribed at an FDA approved dosage.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

**PEMPHIGUS VULGARIS**

**Initial Authorization**

- The medication is being recommended and prescribed by a rheumatologist or dermatologist
- The patient is \( \geq 18 \) years with a diagnosis of moderate to severe pemphigus vulgaris
- Documentation the patient will be receiving P. jirovecii pneumonia (PJP) prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment
- Rituximab is being prescribed at an FDA approved dose/frequency
- Rituximab is being used in combination with a tapering course of glucocorticoids

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.
Reauthorization

- Documentation of clinical benefits (e.g., absence of new lesions) with rituximab therapy was provided by a rheumatologist or dermatologist
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose/frequency

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

ONCOLOGY INDICATIONS

Initial Authorization:

- The medication is being recommended and prescribed by an oncologist.
- The medication is being requested for a labeled indication or the an indication supported by a NCCN category 1, 2A, or 2B level of evidence
- Documentation of CD20 positive disease
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or the National Comprehensive Cancer Network (NCCN) or American Society of Clinical Oncology (ASCO) standard of care guidelines.
- If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.
- If the request is for Rituxan Hycela (rituximab/hyaluronidase human, recombinant),
  - the patient has received at least one full dose of a rituximab product by intravenous infusion,
  - the medication is being requested for a malignant condition, and
  - there is a medical reason why the alternative rituximab product cannot be continued
If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

**Reauthorization**

- The medication is being recommended and prescribed by an oncologist.
- Rituximab is being prescribed at a dose that is within FDA approved guidelines and/or is supported by the medical compendium as defined by the Social Security Act and/or per the NCCN or ASCO standard of care guidelines.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

**GRANULOMATOSIS WITH POLYANGIITIS (GPA) (WEGENER’S GRANULOMATOSIS) AND MICROSCOPIC POLYANGIITIS (MPA):**

**Initial Authorization:**

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- The patient is 2 years of age or older and has a documented clinical diagnosis of GPA (Wegener’s Granulomatosis) or MPA.
- For non-severe disease, the patient has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial of three months (including dates, doses) of glucocorticoid (i.e. prednisone) AND methotrexate or documentation includes a medical reason (intolerance, hypersensitivity, etc.) why patient is not able to use these therapies to manage their medical condition.
- For severe disease, a trial of glucocorticoid and methotrexate is not required.
- Documentation indicating that rituximab is being used concurrently with glucocorticoids.
- Documentation the patient will be receiving PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) during treatment or the prescriber has provided a medical reason for not prescribing PJP prophylaxis.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Rituximab is being prescribed at an FDA approved dosage.
- If the patient is 18 years of age or older, and the request is for any medication other than
Ruxience (rituximab-pvvr), there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- The medication is being recommended and prescribed by a rheumatologist or nephrologist.
- Documentation the patient will continue to receive PJP prophylaxis (ex. TMP/SMX, dapsone, atovaquone) or the prescriber has provided a medical reason for not prescribing PJP prophylaxis
- Rituximab is being prescribed at an FDA approved dose.

If all of the above conditions are met, the request will be approved for up to a 1 year duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

DERMATOMYOSITIS (DM) and POLYMYOSITIS (PM)

Initial Authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Patient meets one of the following:
  - Bohan and Peter score indicating definite DM or PM
  - Bohan and Peter score indicating probable DM or PM AND concurring diagnostic evaluation by ≥ 1 specialist (e.g. neurologist, rheumatologist, dermatologist)
- Patient does NOT have cancer associated myositis defined as myositis within 2 years of cancer diagnosis (except basal or squamous cell skin cancer or carcinoma in situ of the cervix that has been excised and cured)
- One of the following:
  - Patient has a documented trial and failure of, or has a documented medical reason for not using methotrexate (MTX) OR azathioprine
  - Patient has severe, life-threatening weakness or dysphagia
- Rituximab is prescribed at a dose per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Pediatrics (AAP) standard
If the request is for any medication other than Ruxience (rituximab-pvvr) there is a documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g. intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be used.

If all of the above conditions are met, the request will be approved for up to a 1 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

Re-authorization:

- Rituximab is being recommended and prescribed by a neurologist, rheumatologist, or dermatologist.
- Documentation was provided indicating that the patient had clinical benefit from receiving rituximab therapy.
- Rituximab is prescribed at a medically accepted dose per the medical compendia.

If all of the above conditions are met, the request will be approved for up to a 3 month duration; if all of the above criteria are not met, the request is referred to a Medical Director/clinical reviewer for medical necessity review.

OTHER MEDICALLY ACCEPTED INDICATIONS

Initial Authorization:

- The medication is prescribed for a non-FDA approved indication but is considered to be a medically accepted use of the medication per the medical compendia (Micromedex, American Hospital Formulary Service (AHFS), DrugPoints, the Drug Package Insert as defined in the Social Security Act and/or per the American Academy of Neurology (AAN) or American Academy of Pediatrics (AAP) standard of care guidelines and has a Class I, IIa or IIb recommendation.
- The medication is prescribed at a medically accepted dose per the medical compendia as defined above.
- The medication is recommended and prescribed a specialist in the field to treat the member’s respective medical condition.
- Documentation indicating that the patient has been screened for HBV prior to initiation of treatment.
- Documentation was submitted indicating that the member has a documented (consistent with pharmacy claims data, OR for new members to the health plan consistent with medical chart history) adequate trial (including dates, doses of medications) of ALL first
line medical therapies as recommended by the medical compendia and standard care
guidelines and/or has another documented medical reason (e.g. intolerance,
contraindications, etc.) for not receiving or trying all first line medical treatment(s).

- If the request is for any medication other than Ruxience (rituximab-pvvr), there is a
documented trial and failure of Ruxience (rituximab-pvvr), or medical reason why (e.g.
 intolerance, hypersensitivity, contraindication) Ruxience (rituximab-pvvr) cannot be
used.

If all of the above conditions are met, the request will be approved for up to a 3 month duration.
If all of the above criteria are not met, the request is referred to a Medical Director/clinical
reviewer for medical necessity review.

Re-authorization:

- The medication is prescribed at a medically accepted dose per the medical compendia
- The medication is recommended and prescribed a specialist in the field to treat the
member’s respective medical condition.
- Documentation from medical chart was submitted indicating that the member has
significantly clinically benefited from the medication.

If all of the above conditions are met, the request will be approved for up to a 3 month duration.
If all of the above criteria are not met, the request is referred to a Medical Director/clinical
reviewer for medical necessity review.

NOTE: Physician/clinical reviewer must override criteria when, in his/her professional
judgment, the requested item is medically necessary.

Revision/Review Date: 7/2022
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>SMN2 Splicing Modifiers for the Treatment of Spinal Muscular Atrophy (SMA)</td>
</tr>
<tr>
<td>Group Description</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>Evrysdi (risdiplam)</td>
</tr>
<tr>
<td></td>
<td>Spinraza (nusinersen)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), and the Drug Package Insert (PPI).</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>• Concomitant use of Evrysdi and Spinraza</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>For Evrysdi: Patient’s body weight</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a neurologist</td>
</tr>
</tbody>
</table>
| Coverage Duration    | For Evrysdi: If all of the conditions are met, the request will be approved for 6 months for initial approval, followed by 12 months for reauthorization requests.  
For Spinraza: If all of the conditions are met, the request will be approved for 6 months for 5 doses (4 loading doses and 1st maintenance dose) for initial approval, and 12 months for 3 additional maintenance doses for reauthorization requests.  
If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review. |
| Other Criteria       | **Initial approval**  
• Member has a confirmed diagnosis of SMA and the molecular genetic test with mutation analysis was submitted that is positive for the genetic deletion of the exon 7 of the survival motor neuron (SMN1)  
• Baseline motor function or motor milestone achievement was submitted with request [e.g. CHOP Infant Test of Neuromuscular Disorders (CHOP-INTEND) or Hammersmith Infant Neurological Examination (HINE) for Type 1 or Hammersmith Functional Motor Scale Expanded Scores (HFMSE) for Type II and Type III, or 6 minute walk test in subjects able to walk]  
• The request is for an FDA approved dose  
**Reauthorization** |
| Revision/Review Date 1/2023 | • Documentation of clinical response based on the prescriber’s assessment  
• The request is for an FDA approved dose  

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.** |
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Complement Inhibitors</td>
</tr>
<tr>
<td>Drugs</td>
<td>Soliris (eculizumab), Ultomiris (ravulizumab), Empaveli (pegcetacoplan)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, the Drug Package Insert, and/or per the standard of care guidelines</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a hematologist, nephrologist, neurologist, oncologist, or other appropriate specialist.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the initial request will be approved for up to 3 month duration; reauthorization requests will be approved for up to 6 months. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• The request is age appropriate according to FDA approved package labeling or nationally recognized compendia; <strong>AND</strong></td>
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<tr>
<td></td>
<td>• The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient’s diagnosis, age and concomitant medical conditions; <strong>AND</strong></td>
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<td></td>
<td>• Documentation of vaccination against meningococcal disease or a documented medical reason why the patient cannot receive vaccination or vaccination needs to be delayed; <strong>AND</strong></td>
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<td></td>
<td>• Antimicrobial prophylaxis with oral antibiotics (penicillin, or macrolides if penicillin-allergic) for two weeks will be administered if the meningococcal vaccine is administered less than two weeks before starting therapy or a documented medical reason why the patient cannot receive oral antibiotic prophylaxis.</td>
</tr>
<tr>
<td></td>
<td><strong>Paroxysmal Nocturnal Hemoglobinuria (PNH):</strong></td>
</tr>
<tr>
<td></td>
<td>• Documentation of diagnosis by high sensitivity flow cytometry</td>
</tr>
<tr>
<td></td>
<td>• Hemoglobin (Hgb) &lt; 10.5 g/dL</td>
</tr>
</tbody>
</table>
- If the request is for Empaveli (pegcetacoplan), documented trial and failure of, contraindication to, or medical reason for not using Soliris (eculizumab) or Ultomiris (ravulizumab)

**Generalized Myasthenia Gravis (gMG):**
- The request is for Soliris (eculizumab) or Ultomiris (ravulizumab)
- Patient has a positive serologic test for anti-AChR antibodies; **AND**
- Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV at initiation of therapy; **AND**
- Patient has a Myasthenia Gravis-specific Activities of Daily Living scale (MG-ADL) total score $\geq 6$ at initiation of therapy; **AND**
- One of the following:
  - Failed treatment over a total of 1 year or more with 2 or more immunosuppressive therapies (ISTs) either in combination or as monotherapy; **OR**
  - Failed at least 1 IST and required chronic plasmapheresis or plasma exchange or intravenous immunoglobulin; **OR**
  - Has a documented history of contraindications or intolerance to ISTs

**Neuromyelitis Optica Spectrum Disorder (NMOSD)**
- Refer to the “Neuromyelitis Optica Spectrum Disorder (NMOSD) Agents” policy

**Atypical Hemolytic Uremic Syndrome (aHUS)/Complement-Mediated HUS**
- Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies; **OR**
- Provider attestation treatment is being used empirically and delay in therapy will lead to unacceptable risk to the patient

**Re-Authorization:**
- Provider has submitted documentation of clinical response to therapy (e.g., reduction in disease severity, improvement in quality of life scores, reduced need for blood transfusions); **AND**
- The request is for a dose that is FDA approved or in nationally recognized compendia in accordance with the patient’s diagnosis, age, and concomitant medical condition; **AND**
| Revision/Review Date 7/2022 | • If the request is for aHUS/Complement Mediated HUS  
  o Documentation of confirmed diagnosis as evidenced by complement genotyping and complement antibodies  

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.** |
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group</td>
<td>Somatostatin Analogs and Growth Hormone Receptor Antagonists</td>
</tr>
<tr>
<td>Drugs</td>
<td>Octreotide (Sandostatin)</td>
</tr>
<tr>
<td></td>
<td>Sandostatin LAR (octreotide)</td>
</tr>
<tr>
<td></td>
<td>Lanreotide 120 mg/0.5 mL</td>
</tr>
<tr>
<td></td>
<td>Somatuline Depot (lanreotide) 60 mg/0.2 mL, 90 mg/0.3 mL, 120 mg/0.5 mL</td>
</tr>
<tr>
<td></td>
<td>Mycapssa (octreotide)</td>
</tr>
<tr>
<td></td>
<td>Signifor (pasireotide)</td>
</tr>
<tr>
<td></td>
<td>Signifor LAR (pasireotide)</td>
</tr>
<tr>
<td></td>
<td>Somavert (pegvisomant)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food</td>
</tr>
<tr>
<td></td>
<td>and Drug Administration (FDA) Drug Package Insert (PPI).</td>
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<tr>
<td></td>
<td>** Non-FDA approved (i.e. off-label) uses; refer to the “Off-Label Use” policy**</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Per FDA approved package insert</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a specialist with appropriate expertise in treating the</td>
</tr>
<tr>
<td></td>
<td>condition in question (such as an endocrinologist, neurologist/neurosurgeon,</td>
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<tr>
<td></td>
<td>oncologist, etc.). Consultation with appropriate specialist for the condition in</td>
</tr>
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<td></td>
<td>question is also acceptable.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6</td>
</tr>
<tr>
<td></td>
<td>months. For continuation of therapy, the request will be approved for 12 months.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization</strong></td>
</tr>
<tr>
<td></td>
<td>For all FDA approved indications</td>
</tr>
<tr>
<td></td>
<td>• Medication requested is for an FDA approved indication and dose</td>
</tr>
<tr>
<td></td>
<td>• If the provider is requesting therapy with more than one somatostatin analog or</td>
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<tr>
<td></td>
<td>a somatostatin analog and a growth hormone receptor antagonist, then documentation</td>
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<td></td>
<td>must be submitted as to why patient is unable to be treated with monotherapy, or</td>
</tr>
<tr>
<td></td>
<td>a medical reason was provided why monotherapy is not appropriate.</td>
</tr>
<tr>
<td></td>
<td>For Acromegaly</td>
</tr>
<tr>
<td></td>
<td>• Patient has had an inadequate response to, or medical reason why, surgical</td>
</tr>
<tr>
<td></td>
<td>treatment cannot be used.</td>
</tr>
</tbody>
</table>
- If the patient mild disease (e.g. mild signs and symptoms of growth hormone excess, modest elevations in IGF-1) there is a documented trial of a dopamine agonist (e.g. bromocriptine mesylate, cabergoline) at a therapeutically appropriate dose or a documented medical reason why a dopamine agonist cannot be used

- **Additionally for Mycapssa:**
  - Patient has showed clinical response to and tolerates treatment with octreotide or lanreotide therapy
  - Clinical justification is provided as to why patient cannot continue use of injectable somatostatin analog therapy

- **Additionally for Somavert:**
  - Patient has had an inadequate response to therapy with a somatostatin analog, or has a documented medical reason why a somatostatin analog cannot be used

- **Additionally for Signifor LAR:**
  - Patient has had an inadequate response to therapy with either lanreotide (Somatuline Depot) or octreotide (Sandostain, Sandostatin LAR), or has a documented medical reason why these somatostatin analogs cannot be used.

For Cushing’s Disease (pasireotide products only)

- Patient must have had inadequate response, or medical reason why surgical treatment cannot be used

**Reauthorization**

- Medication requested is for an FDA approved indication and dose
- Documentation has been provided that demonstrates a clinical benefit (e.g. improvement in laboratory values, improvement or stabilization of clinical signs/symptoms, etc.)

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Name</td>
<td>Type I Interferon (IFN) Receptor Antagonist</td>
</tr>
<tr>
<td>Drugs</td>
<td>Saphnelo (anifrolumab-fnia)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>• Severe active central nervous system lupus • Active lupus nephritis</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a rheumatologist or in consultation with a rheumatologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong> • Diagnosis of active moderate to severe systemic lupus erythematosus (SLE) • Member has tried all of the following (or there is a medical reason they cannot use these therapies) before Saphnelo: o Hydroxychloroquine + Glucocorticoids o One other immunosuppressant (i.e., methotrexate, azathioprine, calcineurin inhibitors, or mycophenolate) o Benlysta (belimumab), if member has autoantibody-positive SLE • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose <strong>Re-Authorization:</strong> • Documentation or provider attestation of positive clinical response (i.e., reduction in signs and symptoms of SLE, fewer flares, reduced oral corticosteroid use, etc.) • Prescriber attests member will not be using Saphnelo concurrently with Benlysta • Medication is prescribed at an FDA approved dose If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Date</td>
<td>10/2022</td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>-------------------------</td>
<td>------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td>Skysona (elivaldogene autotemcel)</td>
</tr>
<tr>
<td>Group Description</td>
<td>Skysona (elivaldogene autotemcel)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>• Cerebral adrenoleukodystrophy secondary to head trauma</td>
</tr>
<tr>
<td></td>
<td>• Positive for human immunodeficiency virus type 1 or 2</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Required Medical</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Information</td>
<td></td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Prescriber must be a specialist in the disease being treated.</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td></td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all the criteria are met, the initial request will be approved for a one-time treatment.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Member has a diagnosis of early, active cerebral adrenoleukodystrophy (CALD) defined as all of the following:</td>
</tr>
<tr>
<td></td>
<td>o elevated very long chain fatty acid (VLCFA) levels</td>
</tr>
<tr>
<td></td>
<td>o confirmed mutations in the ABCD1 gene</td>
</tr>
<tr>
<td></td>
<td>o asymptomatic or mildly symptomatic (neurologic function score, NFS ≤ 1)</td>
</tr>
<tr>
<td></td>
<td>o Gadolinium enhancement on brain magnetic resonance imaging (MRI) of demyelinating lesions and Loes scores of 0.5-9</td>
</tr>
<tr>
<td></td>
<td>• Member is a male 4-17 years of age</td>
</tr>
<tr>
<td></td>
<td>• Medication is prescribed at an FDA approved dose</td>
</tr>
<tr>
<td></td>
<td>• Member has not had a prior allogeneic hematopoietic stem-cell transplant (HSCT)</td>
</tr>
<tr>
<td></td>
<td>• Member has no HLA-matched sibling donor for HSCT, or a reason why HSCT with matched sibling donor is not appropriate.</td>
</tr>
<tr>
<td></td>
<td><strong>Re-Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>The safety and effectiveness of repeat administration of Skysona have not been evaluated and will not be approved.</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>1/2023</td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization</td>
<td><strong>Desmopressin nasal spray</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td><strong>Desmopressin 1.5 mg/mL nasal spray</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Covered Uses</td>
<td></td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>≥ 11 months</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the criteria are met, the request will be approved with up to a 12 month duration; if the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization</strong></td>
</tr>
<tr>
<td></td>
<td>One of the following:</td>
</tr>
<tr>
<td></td>
<td>- Diagnosis of Hemophilia A with Factor VIII coagulant activity levels greater than 5%.</td>
</tr>
<tr>
<td></td>
<td>- Hemophilia A carrier</td>
</tr>
<tr>
<td></td>
<td>- Diagnosis of mild to moderate Type 1 (classic) von Willebrand’s disease with Factor VIII coagulant activity levels greater than 5%.</td>
</tr>
<tr>
<td></td>
<td>- Diagnosis of mild to moderate Type 2A, 2M, or 2N von Willebrand’s disease and documentation of a desmopressin trial and response</td>
</tr>
<tr>
<td></td>
<td>o A single unit of desmopressin nasal spray will be approved for a desmopressin trial</td>
</tr>
<tr>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
<td></td>
</tr>
</tbody>
</table>

**Revision/Review Date 10/2022**
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Synagis (palivizumab)</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td><strong>Synagis (palivizumab)</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td><strong>Synagis (palivizumab)</strong></td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>A maximum of 5 doses may be approved within the Respiratory Syncytial Virus (RSV) season. Requests for additional doses will be reviewed on a case-by-case basis based on CDC surveillance reports, state/local health department recommendations, and other current medical literature</td>
</tr>
</tbody>
</table>
| Other Criteria               | Infants less than 1 year of age at the onset of the respiratory syncytial virus (RSV) season (which typically starts November 1st, but may vary seasonally) **AND** have one of the following indications:  
  • Born at less than 29 weeks, 0 days gestation  
  • Born at less than 32 weeks, 0 days gestation **AND** had chronic lung disease of prematurity defined as greater than 21% oxygen for at least 28 days after birth  
  • Born at any gestational age with hemodynamically significant heart disease including:  
    o Cyanotic heart disease in consultation with a pediatric cardiologist  
    o Acyanotic Heart disease with one of the following:  
      ▪ On heart failure medication and expected to require cardiac surgical procedure  
      ▪ Moderate to severe pulmonary hypertension  
  • Cystic fibrosis with clinical evidence of chronic lung disease (CLD) and/or nutritional compromise in the first year of life  
  • Born at any gestational age with pulmonary abnormality or neuromuscular disease that impairs the ability to clear secretions from the lower airway  

Infants less than 2 years of age at the onset of the RSV season (which typically starts November 1st, but may vary seasonally) **AND** have one of the following indications:  
• Born at less than 32 weeks, 0 days **AND** had a diagnosis of chronic lung disease of prematurity at birth as defined above |
AND had continued need for one of the following respiratory interventions in the 6 months preceding RSV season: Chronic steroids, chronic diuretics, supplemental oxygen

- Cystic fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight for length less than the 10th percentile
- Born at any gestational age and will be profoundly immunocompromised during the RSV season, including:
  - Solid organ or hematopoietic stem cell transplant recipient
  - Chemotherapy recipient
- Born at any gestational age and receiving a cardiac transplant

Medical Director/clinical reviewer may override criteria when, in his/her professional judgement, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Insulin-Like Growth Factor-I Receptor (Igf-1r) Antagonists For Thyroid Eye Disease</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td>Tepezza (teprotumumab-trbw)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>If all of the criteria are met, the request will be approved for up to 24 weeks of treatment (8 total infusions). Retreatment requests will not be allowed beyond the 8 dose limit.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Member must be 18 years age or older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be an ophthalmologist, endocrinologist, or specialist with expertise in the treatment of Grave’s disease with thyroid eye disease.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td>Other Criteria</td>
<td>Tepezza is approved when all of the following are met:</td>
</tr>
<tr>
<td></td>
<td>• Dosing does not exceed dosing guidelines as outlined in the package insert</td>
</tr>
<tr>
<td></td>
<td>• Patient has a confirmed diagnosis of Graves’ disease</td>
</tr>
<tr>
<td></td>
<td>• Documentation of active moderate-severe thyroid eye disease as evidenced by one or more of the following:</td>
</tr>
<tr>
<td></td>
<td>o Lid retraction of &gt;2mm</td>
</tr>
<tr>
<td></td>
<td>o Moderate or severe soft-tissue involvement</td>
</tr>
<tr>
<td></td>
<td>o Proptosis ≥3mm above normal values for race and sex</td>
</tr>
<tr>
<td></td>
<td>o Periodic or constant diplopia</td>
</tr>
<tr>
<td></td>
<td>• Patient must be euthyroid, thyroxine and free triiodothyronine levels are less than 50% above or below normal limits (submit laboratory results with request), or has been initiated on antithyroid medication.</td>
</tr>
<tr>
<td></td>
<td>• Patients of reproductive potential: attestation the patient is not pregnant, and appropriate contraception methods will be used before, during, and 6 months after the last infusion</td>
</tr>
<tr>
<td></td>
<td>• Patient has had a trial and therapy failure of, or contraindication to, oral or IV glucocorticoids to treat their condition</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td><strong>Re-authorization:</strong></td>
</tr>
<tr>
<td>---------------------</td>
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</tr>
<tr>
<td>4/2023</td>
<td>• Retreatment or renewal requests beyond a total of 24 weeks of treatment (8 total infusions) will not be allowed. Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
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<tr>
<td>----------------------------------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization Group</td>
<td>Tavneos (avacopan)</td>
</tr>
<tr>
<td>Description</td>
<td></td>
</tr>
<tr>
<td>Drugs</td>
<td>Tavneos (avacopan)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Not Applicable</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>≥18 years old</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a rheumatologist or hematologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If the conditions are met, the request will be approved for a 6-month duration for initial requests and a 6-month duration for renewal requests.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Diagnosis of one of the following subtypes of severe active antineutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis: granulomatosis with polyangiitis (GPA) or microscopic polyangiitis (MPA)</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attestation that Tavneos will be prescribed in combination with corticosteroids AND cyclophosphamide or rituximab, unless there is documented trial and failure, intolerance, inability to use, or contraindication to these therapies</td>
</tr>
<tr>
<td></td>
<td>• The prescribed dose is within FDA-approved dosing guidelines</td>
</tr>
<tr>
<td></td>
<td>• Documentation of baseline Birmingham Vasculitis Activity Score (BVAS) score</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attestation that the patient will have liver function tests before treatment (ALT, AST, alkaline phosphate, and total bilirubin) and every 4 weeks after start of therapy for the first 6 months of treatment</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attestation that the patient has been screened for and does not have active hepatitis B virus (HBV) infection at baseline</td>
</tr>
<tr>
<td></td>
<td><strong>Reauthorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Documentation of remission (BVAS score of 0) OR improvement in BVAS score</td>
</tr>
<tr>
<td></td>
<td>• Prescriber attestation that patient has no abnormality in liver function tests (abnormality: ALT or AST &gt;3 times)</td>
</tr>
</tbody>
</table>
| Revision/Review Date: 1/2023 | the upper limit of normal and bilirubin >2 times the upper limit of normal)  
• Prescriber attestation that patient has no active HBV infection  
• The prescribed dose is within FDA approved dosing guidelines  

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.** |
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Tranthyretin-mediated Amyloidosis Agents</td>
</tr>
<tr>
<td>Group Description</td>
<td></td>
</tr>
</tbody>
</table>
| Drugs                      | **Preferred:**  
Polyneurpathy – Onpattro (patisiran), Amvutra (vutrisiran)  
Cardiomyopathy – Vyndaqel (tafamidis meglumine), Vyndamax (tafamidis)  

**Non-preferred:**  
Polyneurpathy – Tegsedi (inoterson)  
Or any other newly marketed agent |
| Covered Uses               | Medically accepted indications are defined using the following sources:  
the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines. |
| Exclusion Criteria         | N/A                                                                                                                                                                                                              |
| Required Medical Information | See “Other Criteria”                                                                                                                                                                                              |
| Age Restrictions           | Patient must be 18 years of age or older                                                                                                                                                                          |
| Prescriber Restrictions    | Prescriber must be neurologist, cardiologist, or specialist in the treatment of amyloidosis                                                                                                                                 |
| Coverage Duration          | If all of the criteria are met, the initial request will be approved for 6 months.  
For continuation of therapy the request will be approved for 6 months.  
If all of the criteria are not met, the request is referred to a Clinical Reviewer for medical necessity review. |
| Other Criteria             | **Initial Authorization:**  
- Regimen does not exceed FDA-approved dose/frequency  
- Patient has not undergone a liver or heart transplant  
- Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, Amvutra,  
- If the request is for Onpattro, Amvutra, or Tegsedi, patient has diagnosis of polyneuropathy of hereditary transthyretin-mediated amyloidosis as evidenced by:  
  - Documented transthyretin variant by genotyping  
  - One of the following:  
    - Patient has baseline polyneuropathy disability (PND) score ≤ IIIb  
    - Patient has a baseline FAP Stage 1 or 2  
    - Patient has baseline neuropathy impairment (NIS) score ≥ 5 and ≤ 130  
      - Patient has clinical signs/symptoms of neuropathy  
      - For Tegsedi, patient has contraindication to/or previous trial and failure of use of Onpattro or Amvutra |
• If the request is for Vyndaqel or Vyndamax, patient has diagnosis of cardiomyopathy of wild-type or hereditary transthyretin-mediated amyloidosis as evidenced by all of the following:
  o Documented transthyretin variant by genotyping or wild-type amyloidosis
  o Documented amyloid deposit by biopsy or positive technetium 99m pyrophosphate (Tc 99m PYP) cardiac imaging
  o Patient has New York Heart Association (NYHA) functional class I, II, or III heart failure symptoms.

Re-authorization (for continuing and new patients to the plan):
• Patient’s regimen does not exceed FDA-approved dose/frequency for the agent
• Patient has not undergone a liver or heart transplant
• Patient is not taking any of these agents concurrently: Tegsedi, Onpattro, Amvuttra,
• Documented positive clinical response to therapy from baseline (stabilization/slowing of disease progression, improved neurological impairment, motor functions, improved NIS score, stabilization/reduced rate of decline in 6 minute walk test, etc.)
• If the request is for Vyndaqel/Vyndamax
  o Patient has continued NYHA functional class I, II, or III heart failure symptoms

Continuation of Therapy/Grandfathering Provision:
Members with history (within the past 90 days) of a non-formulary product are not required to try a formulary agent prior to receiving the non-formulary product.

Medical Director/clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group</td>
<td>Tzield (teplizumab-mzwv)</td>
</tr>
<tr>
<td>Description</td>
<td>Tzield (teplizumab-mzwv)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Type 2 diabetes (T2D)</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>According to package insert</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with an endocrinologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all the criteria are met, the initial request will be approved for a one-time treatment.</td>
</tr>
</tbody>
</table>
| Other Criteria                 | **Initial Authorization:**  
  - Medication is prescribed at an FDA approved dose  
  - Diagnosis of stage 2 type 1 diabetes (T1D) confirmed by presence of at least two of the following autoantibodies:  
    - Glutamic acid decarboxylase 65 (GAD) autoantibody  
    - Insulin autoantibody (IAA)  
    - Insulinoma-associated antigen 2 autoantibody (IA-2A)  
    - Zinc transporter 8 autoantibody (ZnT8A)  
    - Islet cell autoantibody (ICA)  
  - Abnormal glucose on an oral glucose-tolerance test (or alternative glycemic test if an oral glucose-tolerance test is not available) |
<p>| Date: 1/2023                   | <strong>If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.</strong>          |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group</td>
<td>Vijoice</td>
</tr>
<tr>
<td>Description</td>
<td>Vijoice (alpelisib)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>≥ 2 years</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a geneticist, dermatologist, vascular surgeon, hematologist/oncologist, or other specialist in the treatment of PIK3CA-Related Overgrowth Spectrum (PROS)</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
</tbody>
</table>
| Other Criteria             | **Initial Authorization:**  
|                           | • Diagnosis of PROS  
|                           | • Documented evidence of a mutation in the PIK3CA gene  
|                           | • Patient has at least one target lesion identified on imaging  
|                           | • Prescriber attests the patient’s condition is severe or life-threatening and necessitates systemic treatment  
|                           | • Medication is prescribed at an FDA approved dose  
|                           | **Re-Authorization:**  
|                           | • Documentation of a positive clinical response defined as the patient achieving ALL of the following:  
|                           |   o At least a 20% reduction in the sum of measurable target lesion volume (1 to 3 lesions, via central review of imaging scans)  
|                           |   o None of the individual target lesions have ≥ 20% increase from baseline  
|                           |   o Absence of progression of non-target lesions  
|                           |   o Absence of any new lesions  
|                           | • Prescriber attests the patient does not have any serious adverse events or unacceptable toxicity  
|                           | • Medication is prescribed at an FDA approved dose  
<p>| Date: 07/2022              | If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review.                                                                                     |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td><strong>Vimizim (elosulfase alfa)</strong></td>
</tr>
<tr>
<td>Drugs</td>
<td>Vimizim (elosulfase alfa)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “other criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Patient must be 5 years of age or older.</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber is, or is collaborating with another provider who is, a specialist in the treatment of Morquio A syndrome or other lysosomal storage disorders.</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>6 months</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization (new to therapy):</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient has confirmed diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Genetic testing</td>
</tr>
<tr>
<td></td>
<td>o Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts</td>
</tr>
<tr>
<td></td>
<td>• Dosage does not exceed 2 mg/kg once a week.</td>
</tr>
<tr>
<td></td>
<td>• Patient must have completed a 6-minute walk test for baseline evaluation (must submit results with request) and be able to walk a minimum of 30 meters at baseline.</td>
</tr>
<tr>
<td></td>
<td><strong>Re-Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>• Dosage does not exceed 2 mg/kg once a week.</td>
</tr>
<tr>
<td></td>
<td>• Patient shows signs of improvement from baseline in a 6-minute walk test (must submit results with request)</td>
</tr>
<tr>
<td></td>
<td><strong>Re-authorization for members new to the plan previously treated with Vimizim:</strong></td>
</tr>
<tr>
<td></td>
<td>• Patient has confirmed genetic diagnosis of mucopolysaccharidosis IVA (MPS IVA, or Morquio A syndrome) via one of the following:</td>
</tr>
<tr>
<td></td>
<td>o Genetic testing</td>
</tr>
<tr>
<td></td>
<td>o Analysis of N-Acetylgalactosamine 6-sulfatase (GALNS) activity in leukocytes or fibroblasts</td>
</tr>
<tr>
<td></td>
<td>• Dosage does not exceed 2 mg/kg once a week.</td>
</tr>
<tr>
<td></td>
<td>• Patient must have completed a 6-minute walk test for baseline evaluation, and patient shows signs of improvement from baseline in a recent 6-minute walk test (must submit both results with request).</td>
</tr>
</tbody>
</table>
|                                    | • If a baseline 6-minute walk test was not completed prior to initiation of Vimizim therapy, then:
<table>
<thead>
<tr>
<th>Revision/Review Date 7/2022</th>
</tr>
</thead>
<tbody>
<tr>
<td>o A current test must be completed and patient must be able to walk a minimum of 30 meters (must submit results with request).</td>
</tr>
<tr>
<td>o Continued authorizations for Vimizim for patients without a completed baseline 6-minute walk test evaluation prior to initiation of therapy must continue to be able to walk a minimum of 30 meters in subsequent evaluations.</td>
</tr>
<tr>
<td>o If patient is established on Vimizim therapy prior to enrollment on the plan, but is not able to walk a minimum of 30 meters, then medical justification is required as to how the patient continues to receive benefit from Vimizim therapy.</td>
</tr>
</tbody>
</table>

**Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.**
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Verquvo</td>
</tr>
<tr>
<td>Drugs</td>
<td>Verquvo (vericiguat)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Pregnancy</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Patient must be 18 years or older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a cardiologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the conditions are met, the request will be approved for 12 month duration. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td>1. Medication is prescribed at an FDA approved dose</td>
</tr>
<tr>
<td></td>
<td>2. The medication is being used for the treatment of symptomatic chronic heart failure with reduced ejection fraction (less than 45%)</td>
</tr>
<tr>
<td></td>
<td>3. Documentation that the patient has had a previous hospitalization for heart failure or has required outpatient IV diuretics</td>
</tr>
<tr>
<td></td>
<td>4. Member is currently being prescribed, or will be prescribed, one agent from each of the following, or documentation has been provided that the member is not able to tolerate or has a contraindication these agents:</td>
</tr>
<tr>
<td></td>
<td>a. Angiotensin-converting enzyme (ACE) inhibitor OR angiotensin receptor blocker (ARB) OR angiotensin receptor/neprilysin inhibitor</td>
</tr>
<tr>
<td></td>
<td>b. Mineralocorticoid receptor antagonist (e.g. spironolactone)</td>
</tr>
<tr>
<td></td>
<td>c. Evidence based beta-blocker (i.e., bisoprolol, carvedilol, metoprolol succinate)</td>
</tr>
<tr>
<td></td>
<td>5. Documented trial and failure, intolerance, or contraindication to either Entresto, Farxiga, or Jardiance</td>
</tr>
<tr>
<td></td>
<td>6. Patient is not concomitantly using a phosphodiesterase-5 (PDE-5) enzyme inhibitor (e.g. sildenafil)</td>
</tr>
<tr>
<td></td>
<td>7. Negative pregnancy test (for females of reproductive age; as indicated) within 30 days of request</td>
</tr>
<tr>
<td></td>
<td>8. Prescriber attests to discussing with females of reproductive potential the need to use effective forms of contraception during treatment and for one month after stopping treatment</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>Medical Director/Clinical reviewer must override criteria when, in his/her professional judgment, the requested item is medically necessary.</td>
</tr>
<tr>
<td>Field Name</td>
<td>Field Description</td>
</tr>
<tr>
<td>----------------------------</td>
<td>--------------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Prior Authorization Group Description</td>
<td>Vuity</td>
</tr>
<tr>
<td>Drugs</td>
<td>Vuity (pilocarpine HCl ophthalmic solution)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>≥ 40 years</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with an optometrist or ophthalmologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.</td>
</tr>
</tbody>
</table>
| Other Criteria             | **Initial Authorization:**  
  - Diagnosis of presbyopia  
  - Trial and failure or contraindication to corrective lenses (i.e., eye glasses, contact lenses)  
  - Member does not have glaucoma or ocular hypertension  
  - Medication is prescribed at an FDA approved dose  

**Re-Authorization:**  
- Documentation or provider attestation of positive clinical response  
- Medication is prescribed at an FDA approved dose  

If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review. |

Revision/Review Date: 7/2022
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Sleep Disorder Therapy</td>
</tr>
<tr>
<td>Group Description</td>
<td></td>
</tr>
</tbody>
</table>
| Drugs                       | **Formulary status**: Non-formulary, Prior Authorization Required  
- Xyrem (sodium oxybate) solution  
- Xywav (calcium, magnesium, potassium, and sodium oxybates)                                                                                                                                                                                                                                                                                                                                                     |
| Covered Uses                | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.                                                                                                                                                                                                                       |
| Exclusion Criteria          | Xyrem/Xywav: Succinic semialdehyde dehydrogenase deficiency                                                                                                                                                                                                                                                                                                                                                                                  |
| Required Medical Information| See “Other Criteria”                                                                                                                                                                                                                                                                                                                                                                                                                           |
| Age Restrictions            | Per FDA approved prescribing information.                                                                                                                                                                                                                                                                                                                                                                                                     |
| Prescriber Restrictions     | Prescribed by or in consultation with a sleep specialist, neurologist, or other specialist in the treatment of the member’s diagnosis (does not apply for diagnosis of shift-work disorder)                                                                                                                                                                                                                                                                                  |
| Coverage Duration           | If the criteria are met, requests for Xyrem and Xywav will be approved with up to a 3 month duration. If the criteria are not met, the request will be referred to a clinical reviewer for medical necessity review.                                                                                                                                                                                                                                                                               |
| Other Criteria              | **For all requests:**  
- Medication is being prescribed at an FDA approved dose  

**Xyrem/Xywav initial authorization**  
- Medication is not being taken concurrently with sedative hypnotics  
- For a diagnosis of narcolepsy without cataplexy:  
  o Documented trial and failure of, or a medical reason for not using, ALL of the following:  
    ▪ Either modafinil or armodafinil  
    ▪ Sunosi (solriamfetol)  
    ▪ Wakix (pitolisant)  
  - For a diagnosis of narcolepsy with cataplexy:  
    o Documented trial and failure of each of, or medical reason for not using the following:  
      ▪ Wakix (pitolisant)  
  - For a diagnosis of idiopathic hypersomnia (Xywav only):  
    o Patient has a documented trial and failure of, or medical contraindication to, the following:  
      ▪ Modafinil or armodafinil  

**Reauthorization:**  
- Documentation has been submitted indicating member has experienced a clinical benefit from treatment (e.g. improvement on Epworth Sleepiness Score, reduction in frequency of cataplexy attacks)  
- For members with cataplexy: Documentation has been provided that there has been a reduction in frequency of cataplexy attacks.
<p>| Revision/Review Date 10/2022 | Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Natriuretic Peptides for Achondroplasia</td>
</tr>
<tr>
<td>Drugs</td>
<td>Voxzogo (vosoritide)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>Hypochondroplasia or short stature condition other than achondroplasia</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>According to FDA approved prescribing information</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by, or in consultation with, an endocrinologist, medical geneticist, or other specialist for the treatment of achondroplasia</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.</td>
</tr>
</tbody>
</table>
| Other Criteria             | **Initial Authorization:**  
                          | • Member has a diagnosis of achondroplasia as confirmed via genetic testing  
                          | • Prescriber attests patient has open epiphyses  
                          | • Documentation is provided of baseline recent (within the past 6 months) growth velocity ≥1.5 cm/year  
                          | • Medication is prescribed at an FDA approved dose  
                          | **Re-Authorization:**  
                          | • Documentation of positive clinical response to therapy (as demonstrated by improvement over baseline in annualized growth velocity)  
                          | • Prescriber attests patient has open epiphyses  
                          | • Medication is prescribed at an FDA approved dose  
<pre><code>                      | If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review. |
</code></pre>
<p>| Revision/Review Date       | 4/2023                                                                                                                                              |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td>Vyvgart</td>
</tr>
<tr>
<td>Group Description</td>
<td>Vyvgart (efgartigimod)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Information</td>
<td></td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>≥ 18 years</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by or in consultation with a neurologist or rheumatologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all of the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.</td>
</tr>
</tbody>
</table>
| Other Criteria          | **Initial Authorization:**  
  - Diagnosis of generalized myasthenia gravis (gMG)  
  - Patient has a positive serological test for anti-AChR antibodies  
  - Patient has a Myasthenia Gravis Foundation of America (MGFA) clinical classification of class II, III or IV  
  - Patient has an MG-Activities of Daily Living (MG-ADL) score ≥5  
  - Patient has tried and failed, or has contraindication, to 2 or more conventional therapies (i.e. acetylcholinesterase inhibitors, corticosteroids, non-steroidal immunosuppressive therapies)  
  - Medication is prescribed at an FDA approved dose  

**Re-Authorization:**  
- Patient has improved signs and symptoms of MG and/or at least a 2-point improvement in MG-ADL score from pre-treatment baseline  
- Medication is prescribed at an FDA approved dose  

Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Enzyme replacement therapy for acid sphingomyelinase deficiency (ASMD)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Xenpozyme (olipudase alfa-rpcp)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>N/A</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescribed by, or in consultation with, a specialist experienced in the treatment of ASMD</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all the criteria are met, the initial request will be approved for 6 months. For continuation of therapy, the request will be approved for 12 months.</td>
</tr>
</tbody>
</table>
| Other Criteria              | **Initial Authorization:**  
  - Medication is prescribed at an FDA approved dose  
  - Member has a diagnosis of ASMD confirmed by one of the following:  
    - Deficiency in acid sphingomyelinase (ASM) enzyme activity (as measured by peripheral blood leukocytes, cultured skin fibroblasts, or dried blood spots)  
    - Sphingomyelin phosphodiesterase-1 (SMPD1) gene mutation  
  - Member has a clinical presentation consistent with ASMD type B or type A/B  
  - Documentation of members height and weight  
  - Documentation of baseline ALT and AST within 1 month prior to initiation of treatment  

  **Re-Authorization:**  
  - Documentation or provider attestation of positive clinical response (i.e. improvement in splenomegaly, hepatomegaly, pulmonary function, etc.)  
  - Medication is prescribed at an FDA approved dose  

  If all of the above criteria are not met, the request is referred to a Medical Director/Clinical Reviewer for medical necessity review. |
<p>| Date: 1/2023                |                                                                                                                                                                                                                     |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization Group Description</td>
<td>Zolgensma (onasemnogene abeparvovec-xioi)</td>
</tr>
<tr>
<td>Drugs</td>
<td>Zolgensma (onasemnogene abeparvovec-xioi)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
</tbody>
</table>
| Exclusion Criteria                 | • Patient has previously received this medication  
• Advanced spinal muscular atrophy (SMA) (e.g., complete paralysis of limbs, permanent ventilator-dependence)  
• Administration to premature neonates before reaching full-term gestational age | 
| Required Medical Information       | Patient’s body weight                                                                                                                                                                                                |
| Age Restrictions                   | Patient must be less than 2 years of age                                                                                                                                                                             |
| Prescriber Restrictions            | Neurologist                                                                                                                                                                                                           |
| Coverage Duration                  | Authorization will be placed for 1 dose.                                                                                                                                                                              |
| Other Criteria                     | Patient must meet all of the following criteria:  
• Diagnosis of Spinal Muscular Atrophy (SMA)  
• Bi-allelic mutations in the survival motor neuron 1 (SMN1) gene  
• Baseline anti-AAV9 antibody titers of \( \leq 1:50 \) measured using an enzyme-linked immunosorbent assay (ELISA)  
• Dosing is consistent with FDA approved labeling  

The safety and effectiveness of repeat administration of Zolgensma have not been evaluated and will not be approved. |
<p>| Revision/Review Date               | 10/2022                                                                                                                                                                                                               |
| Medical Director/clinical reviewer  | Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.                                                                     |</p>
<table>
<thead>
<tr>
<th>Field Name</th>
<th>Field Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prior Authorization</td>
<td><strong>Zulresso (brexanolone)</strong></td>
</tr>
<tr>
<td>Group Description</td>
<td>Zulresso (brexanolone)</td>
</tr>
<tr>
<td>Covered Uses</td>
<td>Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.</td>
</tr>
<tr>
<td>Exclusion Criteria</td>
<td>N/A</td>
</tr>
<tr>
<td>Required Medical Information</td>
<td>See “Other Criteria”</td>
</tr>
<tr>
<td>Age Restrictions</td>
<td>Patient must be 15 years of age or older</td>
</tr>
<tr>
<td>Prescriber Restrictions</td>
<td>Prescriber must be a psychiatrist or an obstetrician-gynecologist</td>
</tr>
<tr>
<td>Coverage Duration</td>
<td>If all the criteria are met, the initial request will be approved for a one–time infusion per postpartum period. Continuation after the initial infusion is not indicated for this medication. If all the above criteria are not met, the request must be referred to a Clinical Reviewer for a medical necessity review.</td>
</tr>
<tr>
<td>Other Criteria</td>
<td><strong>Initial Authorization:</strong></td>
</tr>
<tr>
<td></td>
<td>- Diagnosis of moderate to severe postpartum depression (PPD) confirmed by a rating scale such as Montgomery-Åsberg Depression Rating Scale (MADRS) or the Hamilton Rating Scale for Depression (HAM-D) with a score of ≥ 20</td>
</tr>
<tr>
<td></td>
<td>- Patient is ≤ 12 months postpartum with onset of a major depressive episode between the third trimester and 4 weeks after delivery</td>
</tr>
<tr>
<td></td>
<td>- Healthcare facility and patient must be enrolled in the Zulresso REMS program prior to initiation of medication</td>
</tr>
<tr>
<td></td>
<td>- Patient’s weight has been provided and dosing is consistent with FDA approved labeling</td>
</tr>
<tr>
<td>Revision/Review Date</td>
<td>10/2022</td>
</tr>
<tr>
<td>Medical Director/clinical reviewer must override criteria when, in his/her professional judgement, the requested item is medically necessary.</td>
<td></td>
</tr>
</tbody>
</table>
**Field Name** | **Field Description**
---|---
Prior Authorization Group Description | Gene Therapy for Regular Red Blood Cell (RBC) Transfusion Dependent Beta-Thalassemia
Drugs | Zynteglo (betibeglogene autotemcel)
Covered Uses | Medically accepted indications are defined using the following sources: the Food and Drug Administration (FDA), Micromedex, American Hospital Formulary Service (AHFS), United States Pharmacopeia Drug Information for the Healthcare Professional (USP DI), the Drug Package Insert (PPI), or disease state specific standard of care guidelines.
Exclusion Criteria | N/A
Required Medical Information | See “Other Criteria”
Age Restrictions | N/A
Prescriber Restrictions | Prescriber must be a hematologist
Coverage Duration | If all the criteria are met, the initial request will be approved for a one-time treatment. If the conditions are not met, the request will be sent to a Medical Director/clinical reviewer for medical necessity review.
Other Criteria | **Initial Authorization:**
- Medication is prescribed at an FDA approved dose
- Member has a diagnosis of transfusion dependent beta-thalassemia
- Member requires regular RBC transfusions defined as ONE of the following:
  - History of ≥100 mL/kg/year of packed red blood cell (pRBCs) in the past 2 years
  - History of ≥8 transfusions of pRBCs per year in the past 2 years
- Prescriber attests that the member does not have accessibility to a family matched hematopoietic stem-cell transplantation (HSCT)
- Negative pregnancy test (if applicable)
Revision/Review Date: 10/2022

The safety and effectiveness of repeat administration of Zynteglo have not been evaluated and will not be approved.