Keystone Mercy Health Plan, in coordination with PerformRx, has developed a Drug Therapy Management program to help providers more effectively manage their members’ medication therapy regimens. This program is available at no cost to Keystone Mercy Health Plan members.

Drug Therapy Management is a pharmacist-driven program that optimizes drug therapy and addresses patient drug safety concerns. The program uses personalized pharmacist consultations with patients and communication with their providers to optimize drug therapy.

Under the Drug Therapy Management program, our pharmacists will:

- Talk to patients one-on-one
- Send information to patients about their medications and disease states
- Review patients’ medication history to make sure their medicines are safe and effective
- Communicate with their other providers about safety concerns and make recommendations to optimize therapy

This Drug Therapy Management program will not:

- Change your patients’ providers
- Change your patients’ medication regimens
- Change your patients’ pharmacies

We recognize that providers must consider several patient-specific variables when determining the most appropriate drug therapy and any recommendations we make must be evaluated for each individual patient’s needs. If you would like to speak with one of our clinical pharmacists about this program, please call 1-800-486-1991 (TTD/TTY users, please call 1-866-333-5495), between 8:30 a.m. and 5:00 p.m. Eastern time, Monday through Friday.

Your continued support to ensure that our members receive the highest quality health care available is greatly appreciated.

Keystone Mercy Health Plan does not apply copayments to members that are pregnant or post-partum. If at the point of sale the member has a copayment for a submitted claim, an override will be necessary to receive a one-time authorization.

Members should also contact their case-worker to update member eligibility information. Please contact the Pharmacy Help Desk at 1-800-588-6767 for assistance to process the claim.

Access the Keystone Mercy Website 24 hours/7 days a week at www.keystonemercy.com/pharmacy/formulary/online/index.aspx The formulary is updated on a quarterly basis. We recommend adding this link as a favorite in your computer’s web browser for easy access.
FDA Safety Alerts

Overdose Risk with Vitamin D

Contrary to popular belief, an overdose in vitamins can lead to adverse events. This is especially important in the pediatric population because medications are often in liquid formulations and need to be precisely measured prior to administration. Currently, the FDA has come up with a warning regarding the possible overdose of vitamin D.

Vitamin D is essential in calcium absorption and therefore plays an important role in building bones. Supplemental vitamin D is generally recommended in breastfeeding infants because of a lack of it in breast milk. Some vitamin D products come with droppers that can hold more than the daily recommended dose of 400 IU for infants.

Medication use risk can result in an overdose causing undesirable adverse reactions such as nausea, vomiting, constipation, excessive thirst, frequent urination, abdominal pain, muscle weakness, muscle and joint aches, confusion, and fatigue. A more serious side effect such as kidney damage may also occur. Thus, the FDA warns caregivers to exercise extra caution and provides the following recommendations to those administering vitamin D to children:

1. Only droppers that come with the product should be used to administer the vitamin D supplement.
2. Always keep the product in its original package so that alternate caregivers can follow the instructions.
3. It is essential to follow the manufacturer's instructions to avoid potential adverse events.
4. Make sure that the markings on the dropper are clear so that it's easy to draw up the correct dose.
5. Any dosage or administration issues or concerns should be directed toward health care professionals before administering the dose.
6. Finally, before giving a child any vitamin supplements, it is important to consult a health care professional to determine its appropriateness.

References:

Counterfeit Drug Products: An Issue That Is Becoming More Prevalent

Issue:
Counterfeit Drug Products: An Issue That Is Becoming More Prevalent

The issue of counterfeit drug products has become increasingly prevalent in recent years. Counterfeit medications may lack the active ingredients needed to provide the intended therapeutic benefit, and their use can lead to serious adverse events. In some cases, counterfeit medications may contain active ingredients unrelated to the intended therapy, leading to unpredictable outcomes.

Example:

**Example:** An FDA safety alert warned about the use of counterfeit versions of the medication OxyContin. The counterfeit versions were found to contain different active ingredients than the genuine product, leading to potential harm to patients.

**Reference:**

**Relevant Websites:**
1. FDA Consumer Health Information: www.fda.gov/medwatch
2. Counterfeit Medications: www.fda.gov/medwatch

Product Updates

**Table:**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Mechanism of Action</th>
<th>Usual Dose</th>
<th>Dosage Form and Strength</th>
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<tbody>
<tr>
<td>Duloxetine (bupropion)</td>
<td>Management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic for an extended period of time</td>
<td>A partial agonist at 5-opioid and DL-1 (nociceptor) receptors, an antagonist at 5-opioid receptors</td>
<td>Initial dose of 50 mg twice daily up to 150 mg/day</td>
<td>Patch, 5 mg/hour, 10 mg/hour, 20 mg/hour</td>
</tr>
<tr>
<td>Duloxetine (melanie)</td>
<td>Treatment of attention deficit hyperactivity disorder (ADHD) in adolescents (ages 13-17) previously only in children</td>
<td>As a CNS stimulant and blocks the reuptake of noradrenaline and dopamine into the preterminal neurons</td>
<td>Initial dose: 10 mg once daily</td>
<td>Patch, 15 mg/hour, 25 mg/hour, 30 mg/hour</td>
</tr>
<tr>
<td>Duloxetine (mirtazapine)</td>
<td>Treatment of social anxiety in adults</td>
<td>Monoclonal antibody to serotonin receptors</td>
<td>Trials: twice daily of 80 mg (or 200 mg) or 200 mg (or 800 mg)</td>
<td>Oral, 10 mg/30 mg, 100 mg/300 mg</td>
</tr>
<tr>
<td>Infliximab (infliximab)</td>
<td>Treatment of chronic hepatitis C in patients 18 years of age and older with compensated liver disease</td>
<td>Induces an immune response which includes: antinuclear, antiphilatelic, immunomodulatory effects, regulation of all surface major histocompatibility antigens (HLA class-I and class-II expression), and regulation of cytokines expression</td>
<td>Initial dose: 9 mg subcutaneously every 2 weeks for 4 weeks, 15 mg every 3 months; 20 mg repeat every 4 to 6 weeks</td>
<td>IV: 5 mg, 10 mg; SC: 10 mg, 20 mg, 50 mg</td>
</tr>
<tr>
<td>Ivermectin (ivermectin)</td>
<td>Treatment of symptomatic benign prostatic hyperplasia (BPH) in men with an enlarged prostate</td>
<td>Decreases prostatic volume, improves urinary flow rate, and reduces the incidence of chronic prostatitis</td>
<td>Initial dose: 150 mg/day for 14 days</td>
<td>Capsule: 12 mg/4 mg, 24 mg/8 mg</td>
</tr>
<tr>
<td>Levodopa (levodopa)</td>
<td>Prevention of highly and moderately emetogenic cancer chemotherapy, induction, and maintenance: nausea, vomiting, and diarrhea</td>
<td>A selective 5-HT1A receptor antagonist, acting on receptors in vagal nerve terminals and the chemoreceptor trigger zone</td>
<td>3-5 mg oral soluble film given two or three times a day for total dose of 15-20 mg</td>
<td>Oral soluble film: 4 mg, 8 mg</td>
</tr>
</tbody>
</table>

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<tr>
<td>Duloxetine (alprenolol)</td>
<td>Management of moderate to severe chronic pain in patients requiring a continuous, around-the-clock opioid analgesic during an extended period of time</td>
<td>A partial agonist at α-opioid and ORL-1 (nociceptin) receptors, an agonist at δ-opioid receptors, and an antagonist at α-opioid receptors</td>
<td>Initial dose of 5 mg/m^2/hour in opioid-naive patients. Dose may be titrated up to 7.5 mg/m^2/hour</td>
<td>Patch: 5 mg/m^2, 10 mg/m^2, 20 mg/m^2</td>
</tr>
<tr>
<td>Duloxetine (methylxanthine)</td>
<td>Treatment of attention deficit hyperactivity disorder (ADHD) in adolescents (ages 13-17)</td>
<td>Acts as a CBS stimulant and blockade the reuptake of noradrenaline and dopamine into the pre-synaptic neurons</td>
<td>Initial dose: 1 mg once daily. Dose should be titrated and individualized to meet the needs and response of the patient</td>
<td>Patch: 15 mg/24 hours, 30 mg/24 hours, 60 mg/24 hours</td>
</tr>
</tbody>
</table>

References:
2. Infant Overdose Risk With Liquid Vitamin D. FDA Consumer Health Information, June 2010. Available at: http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm232403.htm

Counterfeit Drug Products: An Issue That Is Becoming More Prevalent

The FDA is notifying both consumers and health care professionals about a potentially harmful counterfeit product represented as “Alli” sold over the Internet, particularly at auction sites. The counterfeit version does not contain Alli’s active ingredient, orlistat. Instead the FDA tested revealed that the counterfeit product contained the controlled substance sibutramine. This poses a major health hazard in certain patient populations with a history of cardiovascular disease and would always require physician oversight.

Recommendation: Purchasing counterfeit prescription and non-prescription drugs seems to be an ongoing issue. The FDA is urging consumers to take the following steps to protect themselves from becoming a victim of such matters:

- Purchase products only from legitimate Internet pharmacies that are licensed by the appropriate U.S. Board of Pharmacy.
- When purchasing pharmaceuticals on the Internet, check that the Web site contains a Verified Internet Pharmacy Practice Site Seal, also known as a VIPSSE Seal.
- VIPSSE Seal gives approval by the National Association of Boards of Pharmacy that the pharmacy site meets state licensure requirements.
- Legitimate pharmacies that carry the VIPSSE seal are listed at www.vipsse.info.
- Any questions concerning fraudulent products can be resolved by contacting the drug’s manufacturer directly.

References:
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Issue: The FDA is notifying both consumers and health care professionals about a potentially harmful counterfeit product represented as “Generic Tamiflu” sold over the Internet. FDA tests revealed that the fraudulent product does not contain Tamiflu’s active ingredient, oseltamivir. Instead the tests revealed that the counterfeit product contained clonixin, an ingredient in the same class of antibiotics as penicillin. This poses as a major health hazard for patients who are allergic to penicillin products because they are at risk of experiencing similar reactions from clonixin. This includes a sudden, potentially life-threatening reaction called anaphylaxis, with symptoms that include difficulty breathing, chest tightness, swelling of the throat or tongue, hives, dizziness, loss of consciousness, or a rapid or weak pulse.

In the past, the FDA has also notified both consumers and health care professionals about another potentially harmful counterfeit product represented as “Alli” sold over the Internet, particularly at auction sites. The counterfeit version does not contain Alli’s active ingredient, orlistat. Instead the FDA tests revealed that the counterfeit product contained the controlled substance sibutramine. This poses a major health hazard in certain patient populations with a history of cardiovascular disease and would always require physician oversight.

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(continued on page 3)
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