Clinical Policy Title: Phototherapy and photochemotherapy (PUVA) for skin conditions

Clinical Policy Number: 16.02.04

Effective Date: October 1, 2015
Initial Review Date: May 20, 2015
Most Recent Review Date: June 15, 2016
Next Review Date: June 2017

Policy contains:
- Phototherapy and photochemotherapy.
- Psoralen ultraviolet A (PUVA).

Related policies:
None

ABOUT THIS POLICY: Keystone First has developed clinical policies to assist with making coverage determinations. Keystone First’s clinical policies are based on guidelines from established industry sources, such as the Centers for Medicare & Medicaid Services (CMS), state regulatory agencies, the American Medical Association (AMA), medical specialty professional societies, and peer-reviewed professional literature. These clinical policies along with other sources, such as plan benefits and state and federal laws and regulatory requirements, including any state- or plan-specific definition of “medically necessary,” and the specific facts of the particular situation are considered by Keystone First when making coverage determinations. In the event of conflict between this clinical policy and plan benefits and/or state or federal laws and/or regulatory requirements, the plan benefits and/or state and federal laws and/or regulatory requirements shall control. Keystone First’s clinical policies are for informational purposes only and not intended as medical advice or to direct treatment. Physicians and other health care providers are solely responsible for the treatment decisions for their patients. Keystone First’s clinical policies are reflective of evidence-based medicine at the time of review. As medical science evolves, Keystone First will update its clinical policies as necessary. Keystone First’s clinical policies are not guarantees of payment.

Coverage policy

Keystone First considers the use of phototherapy and photochemotherapy (PUVA) to be clinically proven and, therefore, medically necessary for the following skin conditions after conventional therapies have failed:

- Severe refractory atopic dermatitis/eczema.
- Eosinophilic folliculitis and other pruritic eruptions of HIV infection.
- Mycosis fungoides/Sezary syndrome (cutaneous T-cell lymphoma).
- Severe lichen planus.
- Photodermatoses.
- Pityriasis lichenoides.
- Pityriasis rosea.
- Prurigo nodularis.
- Psoriasis.
- Vitiligo.

Keystone First considers the use of phototherapy at home to be investigational and, therefore, not medically necessary.

**Limitations:**

- PUVA treatments for the above conditions are limited to two to three times per week for 23 weeks and one treatment every one to three weeks thereafter if the patient’s condition improves. If there is not adequate improvement after two months, the treatment is not considered medically necessary thereafter.
- All other uses of PUVA are not medically necessary, including, but not limited to:
  - Keratosis follicularis.
  - Lichen amyloidosis.
  - Lichen myxedematosus.
  - Melasma.
  - Low skin tolerance for sunlight.

**NOTE:** The following codes are not included in the Medicaid medical fee schedule in District of Columbia

96567 - Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (eg, lip) by activation of photosensitive drug(s), each phototherapy exposure session

96913 - Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)

E0691 - Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection; treatment area 2 square feet or less

E0692 - Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 foot panel

E0693 - Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 foot panel

E0694 - Ultraviolet multidirectional light therapy system in 6 foot cabinet, includes bulbs/lamps, timer and eye protection

**Alternative covered services:**

Biologic systemic agents, nonbiologic systemic agents, and phototherapy including broadband (BB-UVB) and narrowband (NB-UVB).
**Background**

Ultraviolet (UV) light — a culprit behind sunburns, wrinkles and skin cancer — can be used in a medical setting as therapy for certain hard-to-treat skin problems and other medical conditions. The main forms of ultraviolet light are ultraviolet A (UVA) and ultraviolet B (UVB).

Psoralen ultraviolet A (PUVA) is a topical treatment of disease by exposure to light at a specific portion of the solar spectrum 320 to 400 nanometers in wavelength. Psoralens are chemicals found in plants that can absorb UV light. PUVA treatment for various skin conditions typically involves administration of an oral drug (e.g., methoxypsoralen) followed by the UV portion 45 to 60 minutes later. Other forms of PUVA include:

- Topical PUVA, with subsequent PUVA exposure.
- Bath PUVA, which is not approved and rarely used in the United States.
- Paint PUVA, used locally on palms and plantar surfaces of the feet with 8-methoxypsoralen ointment or lotion applied directly to lesions.
- Soak PUVA in which the area is immersed in a basin of water containing 8-methoxypsoralen.

Originally PUVA was developed for psoriasis, a relatively common skin disorder. It is also used for conditions such as vitiligo and mycosis fungoides (the most common type of T-cell lymphoma). While mild psoriasis can often be controlled by topical medications, severe cases often require treatments involving UV light exposures.

Before initiating PUVA therapy, other types of treatment should be discussed with the patient. The potential for PUVA to increase the risk of skin cancer, especially when treating psoriasis, should also be discussed. Persons at elevated risk for skin cancer from PUVA include children and persons with a genetic predisposition, a history of skin cancer or a history of at least 150 prior PUVA treatments.

Toxicity to PUVA includes erythema, pruritus, xerosis, irregular pigmentation and gastrointestinal symptoms. Most toxicity can be avoided by altering or dividing the dose. There is an elevated (and dose-dependent) risk of nonmelanoma skin cancer from PUVA (Stern, 1979; Nijsten, 2003). Whether PUVA raises the risk of melanoma is controversial (Stern, 1997; Forman, 1989; Chuang, 1992; Wolff, 1997). When administered to pregnant women, PUVA has been associated with a rise in low-weight births, but not congenital anomalies (Gunnarskog, 1993; Stern, 1991; Garbis, 1995). An expert panel concluded that PUVA is contraindicated for patients with lupus erythematosus, porphyria or xeroderma pigmentosum (Menter, 2010). Caution should be exercised for patients with skin types I and II who tend to burn easily; with a history of arsenic intake; with a likelihood of requiring cyclosporin or methotrexate with previous ionizing radiation therapy; or with a history of melanoma or nonmelanoma skin cancer.

**Searches**

Keystone First searched PubMed and the databases of:

- UK National Health Services Centre for Reviews and Dissemination.
- Agency for Healthcare Research and Quality’s National Guideline Clearinghouse and other evidence-based practice centers.
- The Centers for Medicare & Medicaid Services (CMS).

We conducted searches on May 23, 2016. Search terms were: “Phototherapy” (MeSH),” "Photochemotherapy" (MeSH), “PUVA therapy” and “PUVA therapy home.”
We included:

- **Systematic reviews**, which pool results from multiple studies to achieve larger sample sizes and greater precision of effect estimation than in smaller primary studies. Systematic reviews use predetermined transparent methods to minimize bias, effectively treating the review as a scientific endeavor, and are thus rated highest in evidence-grading hierarchies.
- **Guidelines based on systematic reviews.**
- **Economic analyses**, such as cost-effectiveness, and benefit or utility studies (but not simple cost studies), reporting both costs and outcomes — sometimes referred to as efficiency studies — which also rank near the top of evidence hierarchies.

### Findings

**PUVA used for various skin disorders, PUVA vs. other therapies:**

A number of reports in the medical literature evaluate the efficacy of treatment with PUVA for various skin disorders, both as monotherapy and used concurrently with other treatments. Meta-analyses have produced various findings and weaknesses in methodology of included studies. Meta-analyses by Marsland (2006) and Bailey (2012) found PUVA was more effective when administered concurrently with a second therapy. Chen (2013) showed inconclusive differences between PUVA and NB-UVB in clearing chronic plaque psoriasis and palmoplantar psoriasis, while Ahmutawa (2013) found PUVA superior to NB-UVB and BB-UVB when only monotherapies were addressed. PUVA for vitiligo produced better outcomes compared to placebo and to placebo plus sunlight in repigmentation (Whitton, 2006), while Spuls (1997) established PUVA as superior to UVA and cyclosporine A for obtaining superior outcomes in patients with psoriasis. Both Weberschock (2012) and Whitton (2006) cited problems in methodology and limited usefulness of studies based on small sample sizes, heterogeneous study designs and outcomes measures, and a lack of quality-of-life measures.

Results of several individual comparative studies suggested positive outcomes using PUVA for various indications. Combining oral retinoids with PUVA for psoriasis was more effective compared to monotherapy, using a lower level of exposure (Saurat, 1988; Tanew, 1991). PUVA produced positive results when combined with NB-UVB (Calzavara-Pinton, 1998; Grundmann-Kollmann, 2004; Gordon, 1999) and excimer laser (Trott, 2008). Van Weelden (1990), Hofer (1998) and Tanew (1999) found similar patient outcomes whether persons with skin disorders were treated with PUVA or NB-UVB.

Menter (2010) evaluated different types of uses of PUVA, using the level of evidence grades (I – III) and strength of recommendations (A – C):

<table>
<thead>
<tr>
<th>Agent</th>
<th>Strength of recommendation</th>
<th>Level of evidence</th>
<th>References</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combination of UVB and psoralen plus ultraviolet (PUVA)</td>
<td>C</td>
<td>III</td>
<td>Momtaz and Parrish, 1984; Calzavara-Pinton, 1998; Grundmann-Kollmann et al., 2004</td>
</tr>
<tr>
<td>Topical PUVA</td>
<td>B</td>
<td>II</td>
<td>Cooper, 2000; Collins, 1992</td>
</tr>
<tr>
<td>Oral PUVA</td>
<td>A</td>
<td>I</td>
<td>Henseler, 1981; Melski, 1977</td>
</tr>
<tr>
<td>Combination PUVA and topical agents</td>
<td>A</td>
<td>I</td>
<td>Torras, 2004; Frappaz, 1993</td>
</tr>
</tbody>
</table>
PUVA home administration:

PUVA is usually administered in the outpatient setting, but this treatment is also available for home use. The costs of home therapy are considerably lower, in part because a home light box costs $3,000 to $7,000, compared to $15,000 or more for clinical units (Hayes, 2012). Yertzer (2009) reported that first-year costs of PUVA to patients were $2,590 compared to $3,040 for office use; per-treatment costs to insurers were $5 for home use and $76 for office use.

Milstein (1982) reported on 34 persons, mostly with early mycosis fungoides, treated at home with fluorescent light; the 18-month remission rate of 61 percent and the minimal adverse effects led authors to conclude that home use can be considered in certain cases. A long-term follow-up to this study affirmed that home phototherapy may be a therapeutic option for some (Resnik, 1993). Van Coevorden (2004) compared home PUVA with a portable tanning unit with a hospital-administered bath for 158 patients with chronic hand eczema; results included comparable decreases in eczema for both groups, along with lower travel costs and less work missed for the home group. Raipara (2010) found home NB-UVB was as safe, effective and cost-effective as outpatient treatment and was more convenient and generated higher satisfaction (Raipara, 2010). One study of home-based phototherapy found NB-UVB to be safer than PUVA (Lapolla, 2011). Regular skin examinations by a dermatologist should be performed as PUVA home treatments are conducted.

Policy updates:

We identified four new systematic reviews and meta-analyses, one guideline synthesis, and one synthesis of economic studies for this policy. The clinical indications represented in this update are psoriasis, mycosis, granuloma annulare and vitiligo. Studies of treatments for psoriasis presented the highest-quality evidence of effectiveness. The evidence suggests PUVA and targeted UVB monotherapy are effective first-line treatments for psoriasis based on three randomized controlled trials (RCTs) and multiple case series, but the relative cost-effectiveness of various phototherapy interventions has not been determined (Almutawa, 2015; Hamilton, 2015). PUVA and NB-UVB monotherapy are effective first-line interventions for mycosis fungoides; the effectiveness for PUVA either as maintenance therapy or combined with drugs as first-line therapy is uncertain, but may be beneficial for relapse and late-stage disease (Dogra, 2015). There is insufficient evidence supporting phototherapy as treatment for generalized granuloma annulare (Lukacs, 2015). For treatment of vitiligo, NB-UVB has fewer side effects and is marginally better than PUVA based on three RCTs (Whitton, 2015). These results do not change previous conclusions. Therefore, no changes to the policy are warranted.

Summary of clinical evidence:

<table>
<thead>
<tr>
<th>Citation</th>
<th>Content, Methods, Recommendations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Almutawa (2015; update of 2006 review)</td>
<td>Key points:</td>
</tr>
<tr>
<td>PUVA, UVB and</td>
<td></td>
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<tr>
<td></td>
<td>• Systematic review and meta-analysis of six RCTs and 17 case series.</td>
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<tr>
<td></td>
<td>• The primary outcome was 75% reduction in severity score from baseline.</td>
</tr>
<tr>
<td>Citation</td>
<td>Content, Methods, Recommendations</td>
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</tbody>
</table>
| photodynamic therapy (PDT) for psoriasis | - Overall quality: low with high risk of bias. Small sample size, study heterogeneity.  
- PUVA had a statistically nonsignificant ($P = 0.183$) advantage over targeted UVB. Poled odds ratio based on the random effects model = 3.48 (95% confidence interval [CI] 0.56 – 22.84; three RCTs).  
- The pooled effect estimate of topical PUVA, targeted UVB and PDT were 77%, 61% and 22%, respectively (15-case series).  
- Topical PUVA and targeted UVB phototherapy are effective in treating localized psoriasis. PDT has low efficacy and high percentage of side effects in treating localized psoriasis. |
| Dogra (2015) | **Key points:**  
- Synthesis of 107 systematic reviews, meta-analyses, national guidelines, RCTs, prospective open label studies and retrospective case series.  
- For early stage MF (stage IA, IB, and IIA):  
  - PUVA is a safe, effective and well-tolerated first-line therapy (Level of evidence [LOE] 1+, grade of recommendation B).  
  - NB-UVB is comparable to PUVA but less robust evidence (LOE 2++, Grade of recommendation B).  
  - PUVA with methotrexate, bexarotene or interferon-alpha-2b has unclear advantage over monotherapy.  
  - NB-UVB preferred in patients with patches and thin plaques.  
  - PUVA preferred for thick plaques and relapse after initial NB-UVB therapy.  
- For inducing remission, three treatment sessions per week of either PUVA phototherapy or NB-UVB phototherapy until complete remission.  
- In cases of relapse, PUVA monotherapy or PUVA combined with adjuvants like methotrexate and interferon (LOE 2+, Grade of recommendation B).  
- For late stage MF, above combination therapy may be used as first-line treatment (LOE 3, grade of recommendation C).  
- No consensus regarding maintenance therapy with phototherapy once in remission.  
- Routine maintenance PUVA therapy not recommended; reserved for early relapse after initial course of phototherapy (LOE 2+, Grade of recommendation B).  
- Bath-water PUVA similar efficacy to oral PUVA and may be alternative in case PUVA cannot be administered (LOE 2-, Grade of recommendation C).  
- In pediatric MF and in hypopigmented MF, NB-UVB and PUVA may be tried (LOE 3, grade of recommendation D). |
| Hamilton (2015) | **Key points:**  
- Systematic review of 37 studies reporting 71 comparisons: systemic treatment (45 studies), topical (22 studies), phototherapies (14 studies) and combination (four studies).  
- Cost effectiveness of all therapies remains unclear due to variation in settings, perspective and design.  
- Economic evaluations limited by: lack of high-quality short- and long-term head-to-head comparisons of the effectiveness, safety and adherence of different interventions; comparisons of interventions to placebo, with implicit comparisons of different therapies; absence of patient preferences; and barriers/facilitators to treatment.  
- Primary and secondary integrated clinical and economic research is needed. |
| Lukacs (2015) | **Key points:**  
- Systematic review of individual case reports and small, uncontrolled series. No RCTs.  
- Multiple treatment modalities for GGA were reported including topical and systemic steroids, PUVA and drug therapy.  
- Insufficient evidence. Well-designed RCTs needed. |
| Whitton (2015) | **Key points:**  
- Systematic review of individual case reports and small, uncontrolled series. No RCTs.  
- Multiple treatment modalities for GGA were reported including topical and systemic steroids, PUVA and drug therapy.  
- Insufficient evidence. Well-designed RCTs needed. |
### Citation

**Cochrane review**

**Interventions for vitiligo**

- Systematic review of 96 RCTs (4,512 total participants) of all interventions; three RCTs comparing NB-UVB with PUVA eligible for meta-analysis.
- **Overall quality:** Low with high risk of bias.
- NB-UVB has fewer side effects and is marginally better than PUVA. Proportion of participants achieving > 75% repigmentation favored NB-UVB compared to PUVA (relative risk [RR] 1.60, 95% CI 0.74 to 3.45; I² = 0%).
- NB-UVB group reported less nausea in three studies (RR 0.13, 95% CI 0.02 to 0.69; I² = 0% three studies, N = 156) and erythema in two studies (RR 0.73, 95% CI 0.55 to 0.98; I² = 0%, two studies, N = 106), but not itching in two studies (RR 0.57, 95% CI 0.20 to 1.60; I² = 0%, two studies, N = 106).
- Very few studies only assessed children or included segmental vitiligo.
- There is a need for follow-up studies to assess permanence of repigmentation and high-quality RCTs using standardized measures that address quality of life.

**Glossary**

- **BB-UVB** — Broadband ultraviolet B therapy for skin disorders.
- **Generalized granuloma annulare** — A benign inflammatory dermatosis of unknown cause characterized clinically by dermal papules and annular plaques. Relatively common in all age groups, but rare in infancy.
- **Mycosis fungoides** — The most common type of T-cell lymphoma.
- **NB-UVB** — Narrow band ultraviolet B therapy for skin disorders.
- **Psoriasis** — A common skin disorder characterized by a buildup of cells that form thick, silvery scales and itchy, dry red patches.
- **PUVA** — Psoralen ultraviolet A (the A portion of the solar spectrum, 320 to 400 nanometers in wavelength).
- **Repigmentation** — Restoration of natural skin color.
- **Vitiligo** — A disease that causes the loss of skin color in blotches.

**References**

Professional society guidelines/other:


Peer-reviewed references:


Clinical trials:
Searched clinicaltrials.gov on May 24, 2016 using terms Psoralen OR PUVA | Open Studies. 16 studies found, one relevant.


CMS National Coverage Determinations (NCDs):

Local Coverage Determinations (LCDs):


Commonly submitted codes
Below are the most commonly submitted codes for the service(s)/item(s) subject to this policy. This is not an exhaustive list of codes. Providers are expected to consult the appropriate coding manuals and bill accordingly.

<table>
<thead>
<tr>
<th>CPT Code</th>
<th>Description</th>
<th>Comment</th>
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<tbody>
<tr>
<td>96567</td>
<td>Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (eg, lip) by activation of photosensitive drug(s), each phototherapy exposure session</td>
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<tr>
<td>96912</td>
<td>Photochemotherapy; psoralens and ultraviolet A (PUVA)</td>
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<tr>
<td>96913</td>
<td>Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)</td>
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<table>
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<th>ICD-10 Code</th>
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<td>L20.82</td>
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<td>L20.84</td>
<td>Intrinsic (allergic) eczema</td>
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<td>L40.0</td>
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<td>L40.1</td>
<td>Generalized pustular psoriasis</td>
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<td>L40.2</td>
<td>Acrodermatitis continua</td>
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<td>Pustulosis palmaris et plantaris</td>
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<td>L40.4</td>
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<tr>
<td>L41.0</td>
<td>Pityriasis lichenoides et varioliformis acuta</td>
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<td>Pityriasis lichenoides chronica</td>
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<td>L43.2</td>
<td>Lichenoid drug reaction</td>
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<td>L43.3</td>
<td>Subacute (active) lichen planus</td>
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<td>L57.8</td>
<td>Other skin changes due to chronic exposure to nonionizing radiation</td>
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<tr>
<td>L66.1</td>
<td>Lichen planopilaris</td>
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<td>Perifolliculitis capitis abscedens</td>
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<td>L73.8</td>
<td>Other specified follicular disorders</td>
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<td>L80</td>
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### HCPCS Level II

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<th>Description</th>
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<tbody>
<tr>
<td>E0691</td>
<td>Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection; treatment area 2 square feet or less</td>
</tr>
<tr>
<td>E0692</td>
<td>Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 foot panel</td>
</tr>
<tr>
<td>E0693</td>
<td>Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 foot panel</td>
</tr>
<tr>
<td>E0694</td>
<td>Ultraviolet multidirectional light therapy system in 6 foot cabinet, includes bulbs/lamps, timer and eye protection</td>
</tr>
</tbody>
</table>