FEP Medical Policy Manual

FEP 2.01.47 Light Therapy for Psoriasis

Effective Date: April 15, 2017

Related Policies
2.01.44 Dermatologic Applications of Photodynamic Therapy
2.01.86 Light Therapy for Vitiligo

Light Therapy for Psoriasis

Description
Light therapy for psoriasis includes phototherapy with ultraviolet B (UVB) light boxes, targeted phototherapy, and photochemotherapy with psoralen plus ultraviolet A (PUVA). Targeted phototherapy describes the use of ultraviolet light focused on specific body areas or lesions. PUVA uses a psoralen derivative in conjunction with long wavelength ultraviolet A (UVA) light (sunlight or artificial) for photochemotherapy of skin conditions.

FDA REGULATORY STATUS
In 2001, XTRAC™ (PhotoMedex), a xenon chloride (XeCl) excimer laser, was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of mild-to-moderate psoriasis. The 510(k) clearance was subsequently obtained for a number of targeted ultraviolet B (UVB) lamps and lasers, including newer versions of the XTRAC system (eg, XTRAC Ultra™), the VTRAC™ lamp (PhotoMedex), the BClear™ lamp (Lumenis), and the European manufactured Excilite™ and Excilite µ™ XeCl lamps. FDA product code: FTC.

In 2010, the Levia Personal Targeted Phototherapy® UVB device (Daavlin, Bryan, OH; previously manufactured by Lerner Medical Devices, Los Angeles, CA) was cleared for marketing by FDA through the 510(k) process for home treatment of psoriasis.

The oral psoralen products Oxsoralen-Ultra (methoxsalen soft gelatin capsules) and 8-MOP (methoxsalen hard gelatin capsules) have been approved by FDA; both are made by Valeant Pharmaceuticals. Topical psoralen products have also received FDA approval (eg, Oxsoralen; Valeant Pharmaceuticals).

POLICY STATEMENT
Psoralen plus ultraviolet A (PUVA) for the treatment of severe, disabling psoriasis, which is not responsive to other forms of conservative therapy (eg, topical corticosteroids, coal/tar preparations, ultraviolet light) may be considered medically necessary.

Targeted phototherapy may be considered medically necessary for the treatment of moderate-to-severe localized psoriasis (ie, comprising <20% body area) for which narrowband ultraviolet B or PUVA are indicated.

Targeted phototherapy may be considered medically necessary for the treatment of mild-to-moderate localized psoriasis that is unresponsive to conservative treatment.

Targeted phototherapy is considered investigational for the first-line treatment of mild psoriasis.

The policies contained in the FEP Medical Policy Manual are developed to assist in administering contractual benefits and do not constitute medical advice. They are not intended to replace or substitute for the independent medical judgment of a practitioner or other health care professional in the treatment of an individual member. The Blue Cross and Blue Shield Association does not intend by the FEP Medical Policy Manual, or by any particular medical policy, to recommend, advocate, encourage or discourage any particular medical technologies. Medical decisions relative to medical technologies are to be made strictly by members/patients in consultation with their health care providers. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that the Blue Cross and Blue Shield Service Benefit Plan covers (or pays for) this service or supply for a particular member.
Targeted phototherapy is considered investigative for the treatment of generalized psoriasis or psoriatic arthritis.

**POLICY GUIDELINES**

Disease severity is minimally defined by body surface area (mild psoriasis affects <5% of body surface area, moderate psoriasis affects 5% to 10%, and severe disease affects >10% body surface area). However, lesion characteristics (eg, location and severity of erythema, scaling, induration, pruritus) and impact on quality of life are also taken into account (see references 1-3). For example, while a handprint is equal to approximately 1% body surface area, lesions on the hands, feet, or genitalia that cause disability may be classified as moderate to severe. The Psoriasis Area and Severity Index may be used as an outcome measure in clinical research. Clinical assessment of disease severity is typically qualitative.

Established treatments for psoriasis include use of topical ointments and ultraviolet light (“light lamp”) treatments. Lasers and targeted ultraviolet B lamps are considered equivalent devices; targeted ultraviolet devices are comparable with ultraviolet light panels for treatment purposes. First-line treatment of ultraviolet-sensitive lesions may involve around 6 to 10 office visits; treatment of recalcitrant lesions may involve around 24 to 30 office visits. Maintenance therapy or repeat courses of treatment may be required.

During psoralen plus ultraviolet A (PUVA) therapy, the patient needs to be assessed on a regular basis to determine the effectiveness of the therapy and the development of adverse effects. These evaluations are essential to ensure that the exposure dose of radiation is kept to the minimum compatible with adequate control of disease. Therefore, PUVA is generally not recommended for home therapy.

**BENEFIT APPLICATION**

The BCBS FEP contract stipulates that FDA-approved biologics, drugs and certain devices may not be considered investigational when used for their intended purpose and thus these products may only be assessed based on medical necessity.

**RATIONALE**

Summary of Evidence

For individuals who have mild psoriasis who receive targeted phototherapy, there is little evidence. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Evidence is lacking on the use of targeted phototherapy as first-line treatment of mild psoriasis. In addition, the American Academy of Dermatology does not recommend phototherapy for patients with mild localized psoriasis whose disease can be controlled with topical medications. The evidence is insufficient to determine the effects of the technology on health outcomes.

For individuals who have mild psoriasis that is resistant to topical medications who receive targeted phototherapy, the evidence includes small within-subject studies. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The available pre-post studies have shown that targeted phototherapy can improve mild localized psoriasis (<10% body surface area) that has not responded to topical treatment. Targeted phototherapy is presumed to be safer or at least no riskier than whole body phototherapy, due to risks of exposing the entire skin to the carcinogenic effects of ultraviolet B (UVB) light. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have moderate-to-severe localized psoriasis who receive targeted phototherapy, the evidence includes randomized controlled trials (RCTs) and systematic reviews of RCTs. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity.
Systematic reviews of small RCTs and non-RCTs in patients with moderate-to-severe psoriasis have found that targeted phototherapy has efficacy similar to whole body phototherapy and supports the use of targeted phototherapy for the treatment of moderate-to-severe psoriasis comprising less than 20% of body surface area for which narrowband UVB or photochemotherapy with psoralen plus ultraviolet A (PUVA) are indicated. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

For individuals who have generalized psoriasis who receive PUVA, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. RCTs and systematic reviews of RCTs have found that PUVA is more effective than narrowband UVB, topical steroids, or ultraviolet A without psoralen in patients with generalized psoriasis. In addition, PUVA for psoriasis that has failed topical medication or targeted phototherapy or extensive disease is well-accepted and is recommended by the American Academy of Dermatology. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

American Academy of Dermatology

American Academy of Dermatology 2010 guidelines on the management of psoriasis recommended that patients with psoriasis who are compliant could, under dermatologist supervision, be considered appropriate candidates for home ultraviolet B therapy. Targeted phototherapy was recommended for patients with mild, moderate, or severe psoriasis with less than 10% involvement of the body surface area. Systemic psoralen plus ultraviolet A was indicated in adults with generalized psoriasis resistant to topical therapy.

U.S. Preventive Services Task Force Recommendations

Not applicable.

Medicare National Coverage

Ultraviolet light treatment is covered; targeted phototherapy is not specifically mentioned. There is no national coverage determination on PUVA.

REFERENCES

FEP 2.01.47 Light Therapy for Psoriasis


POLICY HISTORY

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Scope of policy changed to include PUVA for psoriasis. Policy title changed to “Light Therapy for Psoriasis.” Policy statement changed to not medically necessary for the first-line treatment of mild psoriasis, generalized psoriasis or psoriatic arthropitis. Policy statement added that PUVA may be considered medically necessary for the treatment of severe, disabling psoriasis, which is not responsive to other forms of conservative therapy. “Localized” added to second policy statement on targeted phototherapy.</td>
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<tr>
<td>June 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review. No change to policy statements. References 5, 16, &amp; 17 added; others renumbered or removed.</td>
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<tr>
<td>June 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review through October 19, 2016; no references added. Policy statements unchanged.</td>
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