Protocol

Light Therapy for Psoriasis

(20147)

Medical Benefit		**Effective Date**: 07/01/16	**Next Review Date**: 03/21
Preauthorization	Yes	**Review Dates**: 03/16, 03/17, 03/18, 03/19, 03/20	

Preauthorization is required.

The following protocol contains medical necessity criteria that apply for this service. The criteria are also applicable to services provided in the local Medicare Advantage operating area for those members, unless separate Medicare Advantage criteria are indicated. If the criteria are not met, reimbursement will be denied and the patient cannot be billed. Please note that payment for covered services is subject to eligibility and the limitations noted in the patient's contract at the time the services are rendered.

Populations	Interventions	Comparators	Outcomes
Individuals: • With mild localized psoriasis	Interventions of interest are: • Targeted phototherapy	Comparators of interest are: • Topical medications	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With mild psoriasis that is resistant to topical medications	Interventions of interest are: • Targeted phototherapy	Comparators of interest are: • Ultraviolet B light box therapy	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With moderate-to-severe localized psoriasis	Interventions of interest are: • Targeted phototherapy	Comparators of interest are: • Ultraviolet B light box therapy	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity
Individuals: • With generalized psoriasis	Interventions of interest are: • Psoralen plus ultraviolet A	Comparators of interest are: • Topical medications • Ultraviolet B light box therapy	Relevant outcomes include: • Symptoms • Change in disease status • Quality of life • Treatment-related morbidity

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 light (sunlight or artificial) for photochemotherapy of skin conditions.

SUMMARY OF EVIDENCE

For individuals who have mild localized psoriasis who receive targeted phototherapy, there is little evidence.

Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The evidence is lacking on the use of targeted phototherapy as first-line treatment of mild psoriasis. 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 (less than 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 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 phototherapy with 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 psoralens in patients with generalized psoriasis. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

POLICY

Psoralen plus ultraviolet A (PUVA) for the treatment of severe, disabling psoriasis, which is not responsive to other forms of conservative therapy (e.g., 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 (i.e., comprising less than 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.

Targeted phototherapy is considered **investigational** for the treatment of generalized psoriasis or psoriatic arthritis.

POLICY GUIDELINES

Disease severity is minimally defined by body surface area (mild psoriasis affects 5% or less of the body surface area, moderate psoriasis affects 5% to 10%, and severe disease affects more than 10% body surface area). However, lesion characteristics (e.g., location and severity of erythema, scaling, induration, pruritus) and impact on quality of life are also taken into account.[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 (PASI) may be used as an outcome measure in clinical research. Clinical assessment of disease severity is typically qualitative.

Established treatments for psoriasis include the use of topical ointments and ultraviolet light ("light lamp") treatments. Lasers and targeted ultraviolet B lamps are considered equivalent devices; targeted ultraviolet (UV) devices are comparable with UV light panels for treatment purposes. First-line treatment of UV-sensitive lesions may involve around six 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 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.

BACKGROUND

PSORIASIS

Psoriasis is a common chronic immune-mediated disease characterized by skin lesions ranging from minor localized patches to complete body coverage. There are several types of psoriasis; most common is plaque psoriasis, which is associated with red and white scaly patches on the skin. In addition to being a skin disorder, psoriasis can negatively impact many organ systems and is associated with an increased risk of cardiovascular disease, some types of cancer, and autoimmune diseases (e.g., celiac disease, Crohn disease). Although disease severity is minimally defined by body surface area (mild psoriasis affects less than 5% of body surface area, moderate psoriasis affects 5%-10%, and severe disease affects more than 10% of body surface area), lesion characteristics (e.g., location and severity of erythema, scaling, induration, pruritus) and impact on quality of life are also taken into account.[1-3]

Treatment

Topical therapy (e.g., corticosteroids, vitamin D analogues) is generally considered first-line treatments of psoriasis, especially for mild disease. Phototherapy and systemic therapy are treatment options for patients with more extensive and/or severe disease and those who fail conservative treatment with topical agents. Phototherapy is available in various forms including exposure to natural sunlight, use of broadband ultraviolet B devices, narrowband ultraviolet B (NB-UVB) devices, targeted phototherapy, and psoralen plus ultraviolet A (PUVA). NB-UVB is an established treatment for psoriasis, based on efficacy and safety. This evidence review addresses two alternative treatments: targeted phototherapy, which uses ultraviolet light that can be focused on specific body areas or lesions, and PUVA.

Targeted Phototherapy

Potential advantages of targeted phototherapy include the ability to use higher treatment doses and to limit exposure to surrounding tissue. Broadband ultraviolet B devices, which emit wavelengths from 290 to 320 nm, have been largely replaced by NB-UVB devices. NB-UVB devices eliminate wavelengths below 296 nm, which are considered erythemogenic and carcinogenic but not therapeutic. NB-UVB is more effective than broadband ultraviolet B and approaches PUVA in efficacy. Original NB-UVB devices consisted of a Phillips TL-01 fluorescent bulb with a maximum wavelength (lambda max) at 311 nm. Subsequently, an excimer (excited dimer) laser using xenon chloride (XeCl) and lamps were developed as targeted NB-UVB treatment devices; they generate monochromatic or very narrow band radiation with a lambda max of 308 nm. Targeted phototherapy devices are directed at specific lesions or affected areas, thus limiting exposure to the surrounding normal tissues. They may, therefore, allow higher dosages compared with a light box, which could result in fewer treatments to produce clearing. The original indication of the excimer laser was for patients with mild-to-moderate psoriasis, defined as

involvement of less than 10% of the skin. Newer XeCl laser devices are faster and more powerful than the original models, which may allow treatment of patients with more extensive skin involvement (10%-20% body surface area).

Psoralen Plus Ultraviolet A

PUVA uses a psoralen derivative in conjunction with long wavelength ultraviolet A (UVA) light (sunlight or artificial) for photochemotherapy of skin conditions. Psoralens are tricyclic furocoumarin that occur in certain plants and can also be synthesized. They are available in oral and topical forms. Oral PUVA is generally given 1.5 hours before exposure to UVA radiation. Topical PUVA therapy refers to the direct application of the psoralen to the skin with subsequent exposure to UVA light. Bath PUVA is used in some European countries for generalized psoriasis, but the agent used (trimethylpsoralen) is not approved by the Food and Drug Administration (FDA). Paint PUVA and soak PUVA are other forms of topical application of psoralen and are often used for psoriasis localized to the palms and soles. In paint PUVA, 8-methoxypsoralen in ointment or lotion form is put directly on the lesions. With soak PUVA, the affected areas of the body are placed in a basin of water containing psoralen. With topical PUVA, UVA exposure is generally administered within 30 minutes of psoralen application.

PUVA has most commonly been used to treat severe psoriasis, for which there is no generally accepted first-line treatment. Each treatment option (e.g., systemic therapies such as methotrexate, phototherapy, and biologic therapies) has associated benefits and risks. Common minor toxicities associated with PUVA include erythema, pruritus, irregular pigmentation, and gastrointestinal tract symptoms; they generally can be managed by altering the dose of psoralen or ultraviolet light. Potential long-term effects include photoaging and skin cancer, particularly squamous cell carcinoma and possibly malignant melanoma. PUVA is generally considered more effective than targeted phototherapy for the treatment of psoriasis. However, the requirement of systemic exposure and the higher risk of adverse reactions (including a higher carcinogenic risk) have generally limited PUVA therapy to patients with more severe disease.

REGULATORY STATUS

In 2001, XTRAC™ (PhotoMedex), a XeCl excimer laser, was cleared for marketing by the 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 UVB lamps and lasers, including newer versions of the XTRAC system (e.g., 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; previously manufactured by Lerner Medical Devices) was cleared for marketing by the 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 the FDA; both are made by Valeant Pharmaceuticals. Topical psoralen products have also received FDA approval (e.g., Oxsoralen; Valeant Pharmaceuticals).

RELATED PROTOCOLS

Dermatologic Applications of Photodynamic Therapy

Targeted Phototherapy and Psoralen with Ultraviolet A for Vitiligo

Services that are the subject of a clinical trial do not meet our Technology Assessment and Medically Necessary Services Protocol criteria and are considered investigational. *For explanation of experimental and investigational, please refer to the Technology Assessment and Medically Necessary Services Protocol.*

It is expected that only appropriate and medically necessary services will be rendered. We reserve the right to conduct prepayment and postpayment reviews to assess the medical appropriateness of the above-referenced procedures. **Some of this protocol may not pertain to the patients you provide care to, as it may relate to products that are not available in your geographic area.**

REFERENCES

We are not responsible for the continuing viability of web site addresses that may be listed in any references below.

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