

Medical Policy



Title: Ultraviolet Light Therapy for Skin Conditions

Professional

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DESCRIPTION

Ultraviolet (UV) light therapy, including phototherapy, targeted phototherapy and photochemotherapy with psoralen plus ultraviolet A (PUVA), is used for the treatment of certain skin conditions. Phototherapy utilizes UVB light, categorized as either wide-band or narrow-band, which refers to the wavelengths included in the UV light source.

Targeted phototherapy describes the use of ultraviolet light that can be 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.

Background

Phototherapy (e.g., actinotherapy) is defined as exposure to non-ionizing, ultraviolet (UV) radiation for therapeutic benefit by inducing DNA damage. The therapy involves exposure to type A ultraviolet (UVA) radiation or type B ultraviolet (UVB) radiation or

various combinations of UVA and UVB. The differences in these ultraviolet light forms are the length of the waves. UVA wavelength is 320-400 nanometers (NM), broadband (bb) UVB is 280-320 nm and narrowband (nb) UVB is 311-312 nm. UVA is further broken down into UVA1 (340-400nm) and UVA2 (320-340nm). The longer wavelengths emit a lower energy level. UVA bulbs, for example, are used in tanning beds for cosmetic effects because they promote tanning using lower energy with less erythema than UVB.

Psoralens with UVA uses a psoralen derivative in conjunction with long wavelength UVA light (sunlight or artificial) for photochemotherapy of skin conditions. Psoralens are tricyclic furocoumarins 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 directly applying 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 U.S. 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 (8-MOP) in an 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, biologic therapies, etc.) has associated benefits and risks. Common minor toxicities associated with PUVA include erythema, pruritus, irregular pigmentation, and gastrointestinal tract symptoms; these generally can be managed by altering the dose of psoralen or UV 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 cases.

Potential advantages of targeted phototherapy include the ability to use higher treatment doses and to limit exposure to surrounding tissue. Broadband ultraviolet B (BB-UVB) devices, which emit wavelengths from 290 to 320 nm, have been largely replaced by narrowband (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 BB-UVB and approaches PUVA in efficacy. Original NB-UVB devices consisted of a Phillips TL-01 fluorescent bulb with a maximum wavelength (λ_{max}) at 311 nm. Subsequently, xenon chloride (XeCl) lasers and lamps were developed as targeted NB-UVB treatment devices; they generate monochromatic or very narrow band radiation with a λ_{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. Typically, these patients have not been considered candidates for light box therapy, because the risks of exposing the entire skin to the carcinogenic effects of UVB light may outweigh the benefits of treating a small number of lesions. 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% of body surface area. The American Academy of Dermatology does not recommend phototherapy for patients with mild localized psoriasis whose disease can be controlled with topical medications.(1) A variety of topical agents are available including steroids, coal tar, vitamin D analogs (e.g., calcipotriol and calcitriol), tazarotene, and anthralin.

Regulatory Status

In 2001, an XeCl excimer laser (XTRAC™ by PhotoMedex) received 510(k) clearance from the FDA for the treatment of skin conditions such as mild to moderate psoriasis and vitiligo. The 510(k) clearance has subsequently been obtained for a number of targeted UVB lamps and lasers, including newer versions of the XTRAC system including the XTRAC Ultra™, the VTRAC™ lamp (PhotoMedex), the BClear™ lamp (Lumenis), and the European manufactured Excilite™ and Excilite μ™ XeCl lamps.

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, e.g., Oxsoralen® (Valeant Pharmaceuticals).

POLICY

- A. Phototherapy/actinotherapy with UVA is considered **medically necessary** for the following conditions when moderate to severe and refractory to standard therapies:
1. Psoriasis
 2. Eczema (atopic dermatitis)
 3. Eosinophilic folliculitis and other skin eruptions of HIV
 4. Lichen planus
 5. Morphea
 6. Parapsoriasis
 7. Photodermatoses
 8. Mycosis fungoides
 9. Vitiligo
 - For up to 24 weeks, 3 treatments per week until improvement or clearing is considered **medically necessary**.

- B. 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, and ultraviolet light), may be considered **medically necessary**.
- For up to 24 weeks, 2-3 PUVA treatments per week (Monday, Wednesday, Friday or Tuesday, Thursday, Saturday) are considered **medically necessary** for psoriasis until improvement or clearing.
 - Tapered treatments of twice a week then once a week upon improvement (after 24 weeks) may be considered **medically necessary**. Remissions may last between 3-6 months.
 - Remission therapy of 1-4 treatments per month depending on the severity of the psoriasis may be considered **medically necessary**.
- C. PUVA for the treatment of vitiligo which is not responsive to other forms of conservative therapy (e.g., topical corticosteroids, coal/tar preparations, and ultraviolet light) may be considered **medically necessary**.
- D. Targeted phototherapy may be considered **medically necessary** for the treatment of moderate to severe localized psoriasis for which NB-UVB or PUVA are indicated.
- E. Targeted phototherapy may be considered **medically necessary** for the treatment of mild to moderate localized psoriasis that is unresponsive to conservative treatment.
- F. Targeted phototherapy is considered **experimental / investigational** for the treatment of:
1. generalized psoriasis,
 2. vitiligo.
- G. Home phototherapy is considered **experimental / investigational**.

POLICY GUIDELINES

1. Although disease severity is minimally defined by body surface area (mild psoriasis affects less than 5% of the body's surface area, moderate psoriasis affects 5% to 10%, and severe disease affects more than 10% body surface area), lesion characteristics (eg, location and severity of erythema, scaling, induration, pruritus) and impact on quality of life are also taken into account.(2-4) For example, while 1 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. While the Psoriasis Area and Severity Index (PASI) may be used as an outcome measure in clinical research, clinical assessment of disease severity is qualitative.
2. Established treatments for psoriasis include use of topical ointments and ultraviolet light ("light lamp") treatments. Lasers and targeted ultraviolet B (UVB) lamps are considered equivalent devices; targeted UV devices are comparable with UV light panels for treatment purposes. First-line treatment of UV-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.

3. Phototherapy and PUVA are contraindicated in patients with xeroderma pigmentosum, disorders with significant light sensitivity (e.g., albinism), and lupus erythematosus.
4. PUVA is contraindicated in patients who:
 - a. are breast-feeding
 - b. are pregnant
 - c. have a history of melanoma
 - d. have a past history of non-melanoma skin cancer
 - e. have extensive solar damage
 - f. have had previous treatment with ionizing arsenic
 - g. have uremia and hepatic failure, but phototherapy may be used.
5. Phototherapy and PUVA should be used with caution in patients with one or more of the following:
 - a. Family history of melanoma
 - b. Pemphigus or pemphigoid
 - c. Immunosuppression
 - d. Cataracts and aphakia
 - e. Photosensitivity.
6. During a course of 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.

RATIONALE

Targeted Phototherapy

There are several systematic reviews of the literature on targeted phototherapy. Reviews differed in the type of study they included and in the comparison interventions. In a 2013 systematic review by Almutawa et al, PUVA was the comparison intervention and only evidence from randomized controlled trials (RCTs) was considered.⁽⁴⁾ The authors identified 3 RCTs comparing the efficacy of targeted UVB phototherapy with PUVA for treatment of plaque psoriasis. Two of the 3 studies used an excimer laser (308-nm) as the source of targeted phototherapy, and the third study used localized NB-UVB light. There was heterogeneity among studies, and thus a random effects meta-analysis model was used. Using the random effects model, there was not a statistically significant difference between the 2 techniques in the proportion of patients with at least a 75% reduction in psoriasis. The pooled odds ratio (OR) was 3.48, 95% confidence interval (CI), 0.56 to 22.84. (The wide confidence interval indicated a lack of precision in the efficacy estimate). The trials in the systematic review included a study by Neumann et al in which 10 patients were treated with a NB-UVB lamp or cream PUVA.⁽⁵⁾ The UVB lamp and PUVA-treated sides showed similar gradual clearing over the course of 20 treatments, reaching 64% clearance at the end of the 5-week treatment period. In another trial, Sezer et al conducted a left-to-right comparison of local NB-UVB versus PUVA paint (3 times per week for 9 weeks) in a cohort of 25 patients.⁽⁶⁾ The mean severity index improved by 61% with local NB-UVB and 85% with PUVA

paint; 1 patient dropped out of the study because of a phototoxic reaction in the PUVA-paint-treated side.

In 2012, Mudigonda et al published a systematic review of controlled studies (RCTs and non-RCTs) on targeted versus non-targeted phototherapy for patients with localized psoriasis.(7) The authors identified 3 prospective non-randomized studies comparing the 308-nm excimer laser with NB-UVB; no studies comparing the excimer laser with BB-UVB or PUVA were identified. Among the 3 studies was one by Goldinger et al that compared the excimer laser with full-body NB-UVB in 16 patients.(8) At the end of 20 treatments, the PASI scores were equally reduced on the 2 sides, from a baseline of 11.8 to 6.3 for laser and from 11.8 to 6.9 for non-targeted NB-UVB. Another study, by Kollner et al, included 15 patients with stable plaque psoriasis.(9) The study compared the 308-nm laser, the 308-nm excimer lamp, and standard TL-01 lamps. One psoriatic lesion per patient was treated with each therapy (i.e., each patient received all 3 treatments). The investigators found no significant difference in the efficacy of the 3 treatments after 10 weeks. The mean number of treatments to achieve clearance of lesions was 24.

Another systematic review by Mudigonda et al included non-controlled observational studies on targeted UVB phototherapy.(10) This article was not limited to the 308-nm excimer laser as was the 2012 review, previously discussed.(7) A total of 9 studies with at least 7 patients were identified; sample sizes ranged from 7 to 124. The authors concluded that the 308-nm excimer laser, 308-nm excimer nonlaser, and nonexcimer light devices are effective for treating localized psoriasis and are safer than whole body phototherapy because uninvolved skin is spared. The review did not pool study findings and, did not evaluate separately studies by severity of psoriasis.

PUVA

Several systematic reviews have been published. As previously noted, Almutawa et al conducted a pooled analysis of 3 RCTS, 2 of which used an excimer laser, and did not find a statistically significant difference in the efficacy of PUVA and targeted phototherapy in patients with plaque psoriasis.(7) A 2012 industry-sponsored systematic review by Archier et al focused on studies comparing PUVA with NB-UVB in patients with chronic plaque psoriasis.(11) A pooled analysis of 3 RCTS found a significantly higher psoriasis clearance with PUVA compared with NB-UVB (OR=2.79; 95% CI, 1.40 to 5.55). In (OR=2.73; 95% CI, 1.18 to 6.27).

A 2013 RCT used a psoralen formulation available in India, which has the active ingredient methoxsalen; this ingredient is available in the U.S.(4) The study included 45 patients with vitiligo covering more than 5% of their body surface area; 40 patients completed the study. Patients were randomized to receive 3 weekly treatments of either NB-UVB or PUVA. Treatments continued for 60 sessions or 6 months, whichever came first. At the end of follow-up, the mean percentage reduction in the Vitiligo Area Severity Index (VASI) score was 21.7 in the NB-UVB group and 29.2 in the PUVA group. The difference between groups in the VASI score was statistically significant, favoring the PUVA group (p=004). Four patients in the NB-UVB group and 10 in the PUVA group developed adverse effects; none of these were serious enough to lead to discontinuation of phototherapy.

Representative recent RCTs evaluating PUVA for treating psoriasis are described next:

In 2011, Amirnia et al published a study from Iran in which 88 patients with moderate plaque psoriasis were randomized to receive PUVA or topical steroids.(12) Treatment was continued for 4 months or until clearance was achieved. Clearance was defined as disappearance of at least 90% of baseline lesions. All patients in both groups achieved clearance within the 4-month treatment period. Recurrence (defined as a resurgence of at least 50% of the baseline lesions) occurred significantly more often in the topical steroid group (9 of 44, 20.5%) than in the PUVA group (3 of 44, 6.8%), ($p=0.007$).

In 2009, Sivanesan et al published a double-blind RCT evaluating the efficacy of 8-MOP PUVA treatment in patients 18 years and older with moderate to severe psoriasis affecting at least 10% of their body surface area.(13) The study included 40 patients, 30 randomly assigned to receive PUVA and 10 to receive UVA plus placebo psoralens. After a washout period of 2 weeks for topical psoriasis medications and 4 weeks for phototherapy and systemic therapies, patients were treated 3 times a week for 12 weeks. A total of 28 patients completed the study, 21 in the PUVA group and 7 in the UVA plus placebo group. The primary outcome was at least a 75% improvement in the Psoriasis Area and Severity Index score (PASI 75). In an intention-to-treat analysis with the last observation carried forward to analysis at 12 weeks, 19 of 30 (63%) in the PUVA group and 0 of 10 (0%) in the UVA with placebo group achieved at least a 75% improvement in the PASI 7 score ($p<0.001$). In the per protocol analysis, 18 of 21 (86%) in the PUVA group and 0 of 7 (0%) in the placebo group achieved PASI 75. There were no serious adverse effects. The study found a dramatic treatment benefit with PUVA compared with UVA plus placebo; however, there was substantial drop-out and no long-term follow-up.

Two RCTs from India compared outcomes after treatment with oral methoxsalen PUVA and NB-UVB. In 2011, Chauhan et al included 51 patients with plaque psoriasis involving greater than 20% of their body surface area.(14) Patients received treatment with NB-UVB or PUVA 3 times a week. Treatment continued until greater than 75% clearance was attained or for a maximum of 16 weeks. A total of 43 of 51 (84%) patients completed the study. Marked improvement (>75% clearance) was seen in 17 of 21 (90.9%) study completers in the NB-UVB group and 18 of 22 (81.8%) in the PUVA group; $p>0.05$. The mean time to achieve results was also similar in the 2 groups, a mean of 9.9 weeks with each treatment. A 2010 study by Dayal et al randomly weekly NB-UVB phototherapy ($n=30$). (15) After the 3-month treatment period, all patients in both groups had at least 75% clearance of psoriasis or complete clearance. The PASI score did not differ significantly between groups (mean of 1.39 in the PUVA group and 1.61 in the NB-UVB group). The mean number of treatments to achieve clearance, however, was significantly higher in the NB-UVB group than the PUVA group, 16.4 and 12.7, respectively.

Phototherapy

Walker and Jacobe stated that dermatologists are presented with a diversity of therapeutic modalities for the treatment of inflammatory, sclerosing, and neoplastic conditions, but with the development of various new irradiation devices that utilize specific parts of the electromagnetic spectrum, phototherapy has become a more viable, accessible, and effective option in the treatment of these conditions.(16) The UV range (10 to 400 nm) is further sub-divided into UVA and UVB, each of which has been particularly useful in a number of skin conditions. The most commonly used forms of UV irradiation are UVA1, PUVA, and NB-UVB. Each of these modalities differ in their mechanism of action, indications, and side effect profiles, and it is important that clinicians be familiar with these differences. Today, phototherapy is a valuable option in the treatment of many non-psoriatic conditions including AD, sclerosing skin conditions such as

morphea, vitiligo, and mycosis fungoides. Due to its relative safety, phototherapy may be used in most populations, including children and pregnant women. However, contraindications and side effects are known and should be considered before patients begin a phototherapeutic regimen. Again, this study did not mention PMLE as an indication of BB-UVB or NB-UVB.

SUMMARY

Evidence supports the safety and effectiveness of phototherapy and photochemotherapy for the treatment of certain dermatologic conditions that are unresponsive to conventional medical management including: psoriasis, eczema (atopic dermatitis), eosinophilic folliculitis and other skin eruptions of HIV, lichen planus, morphea, parapsoriasis, photodermatoses, mycosis fungoides, and vitiligo. Professional societies and evidence in the published peer-reviewed scientific literature support excimer laser therapy for the treatment of patients with psoriasis who are unresponsive to topical agents and/or phototherapy.

Based on the available evidence and clinical guidelines, PUVA may be considered medically necessary in patients with vitiligo who have not responded adequately to conservative therapy.

Practice Guidelines and Position Statements

American Academy of Dermatology: Their 2010 Guidelines on the management of psoriasis state that targeted phototherapy with the monochromatic XeCl excimer laser can clear psoriasis but that there is limited information on the optimal dosage, scheduling of excimer laser therapy, and duration of remission.(1) Recommendations on PUVA are as follows:

- Systemic PUVA with ultraviolet A is indicated in adults with generalized psoriasis who are resistant to topical therapy.
- There are no studies in children; systemic PUVA may be used with caution in individuals less than 18 years.
- Systemic PUVA is contraindicated in patients with known lupus erythematosus, porphyria, or xeroderma pigmentosum.
- Caution is recommended for several groups of patients including those with skin types I and II, and pregnant and nursing women.

CODING

The following codes for treatment and procedures applicable to this policy are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

CPT/HCPCS

96900	Actinotherapy (ultraviolet light)
96912	Photochemotherapy; psoralens, and ultraviolet A (PUVA)
96920	Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm
96921	Total area 250-500 sq cm
96922	Total area over 500 sq cm
J8999	Prescription drug, oral, chemotherapeutic, not otherwise specified

- In 2002, CPT established separate codes (96920-96922) that describe ultraviolet light laser treatment for inflammatory disease (psoriasis) according to the surface area of skin treated (total area <250 cm², 250 cm²–500 cm², >500 cm²).
- The laser treatment codes are distinct from codes that describe the dermatologic use of ultraviolet light, also known as actinotherapy (96900), and photochemotherapy (96910-96913).

ICD-9 Diagnoses

042	Human immunodeficiency virus [HIV] disease
202.10	Mycosis fungoides, unspecified site, extranodal and solid organ sites
202.11	Mycosis fungoides of lymph nodes of head, face, and neck
202.12	Mycosis fungoides of intrathoracic lymph nodes
202.13	Mycosis fungoides of intra-abdominal lymph nodes
202.14	Mycosis fungoides of lymph nodes of axilla and upper limb
202.15	Mycosis fungoides of lymph nodes of inguinal region and lower limb
202.16	Mycosis fungoides of intrapelvic lymph nodes
202.17	Mycosis fungoides of spleen
202.18	Mycosis fungoides of lymph nodes of multiple sites
691.8	Other atopic dermatitis and related conditions
692.72	Acute dermatitis due to solar radiation
692.82	Dermatitis due to other radiation
696.1	Other psoriasis
696.2	Parapsoriasis
697.0	Lichen planus
698.8	Other specified pruritic conditions
701.0	Circumscribed scleroderma
704.8	Other specified diseases of hair and hair follicles
709.01	Vitiligo

ICD-10 Diagnoses (Effective October 1, 2015)

B20	Human immunodeficiency virus (HIV) disease
C84.00	Mycosis fungoides, unspecified site
L30.9	Dermatitis, unspecified
L40.0	Psoriasis vulgaris
L40.1	Generalized pustular psoriasis
L40.4	Guttate psoriasis
L40.50	Arthropathic psoriasis, unspecified
L40.51	Distal interphalangeal psoriatic arthropathy
L40.52	Psoriatic arthritis mutilans
L40.53	Psoriatic spondylitis
L40.54	Psoriatic juvenile arthropathy
L40.59	Other psoriatic arthropathy
L40.8	Other psoriasis
L40.9	Psoriasis, unspecified
L41.8	Other parapsoriasis
L41.9	Parapsoriasis, unspecified
L43.0	Hypertrophic lichen plans

L43.1	Bullous lichen planus
L43.3	Subacute (active) lichen planus
L43.8	Other lichen planus
L43.9	Lichen planus, unspecified
L56.8	Other specified acute skin changes due to ultraviolet radiation
L56.9	Acute skin change due to ultraviolet radiation, unspecified
L73.9	Follicular disorder, unspecified
L80	Vitiligo
L94.0	Localized scleroderma (morphea)

REVISIONS

09-28-2014	Policy added to the bcbsks.com web site.
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