



Kansas City

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Light Therapy for Psoriasis and Eczema

Policy Number: 2.01.47

Last Review: 5/2014

Origination: 5/2006

Next Review: 5/2015

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for light therapy when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

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**.

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 NB-UVB 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 may be considered **medically necessary** for the treatment of eczema with the presence of skin complications (e.g. bleeding, infection) that has been unresponsive to conservative treatment (topical drugs, oral corticosteroids, immunomodulators, and immunosuppressants).

When Policy Topic is not covered

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.

Considerations

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 (e.g., location and severity of erythema, scaling, induration, and pruritus) and impact on quality of life are also taken into account. (2-4) For example, while one 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.

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 less than 250 sq cm, 250 sq cm–500 sq cm, over 500 sq cm).

The laser treatment codes are distinct from codes that describe the dermatological use of ultraviolet light, also known as actinotherapy (96900), and photochemotherapy (96910-96913).

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 to UV light panels for treatment purposes. First-line treatment of UV-sensitive lesions may involve around 6–10 office visits; treatment of recalcitrant lesions may involve around 24–30 office visits. Maintenance therapy or repeat courses of treatment may be required.

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.

Description of Procedure or Service

Light therapy for psoriasis includes both targeted phototherapy and photochemotherapy with psoralen plus ultraviolet A (PUVA). 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

Psoralens with ultraviolet A (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, pruritis, 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 (SCC) 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 to 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, since 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 analogues (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 U.S. Food and Drug Administration (FDA) for the treatment of mild to moderate psoriasis. 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 the FDA; both are made by Valeant Pharmaceuticals. Topical psoralen products have also received FDA approval e.g., Oxsoralen (Valeant Pharmaceuticals).

Rationale

This policy was originally created in 2001 and was updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period January 8, 2013 through January 2, 2014. Following is a summary of the literature to date on light therapy for psoriasis:

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, psoralen plus ultraviolet A (PUVA) was the comparison intervention and only evidence from randomized controlled trials (RCTs) was considered.(5) The authors identified 3 RCTs comparing the efficacy of targeted ultraviolet B (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 narrowband (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.(6) 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.(7) 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 nontargeted phototherapy for patients with localized psoriasis.(8) The authors identified 3 prospective nonrandomized 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. (9) 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 nontargeted NB-UVB. Another study, by Kollner et al, included 15

patients with stable plaque psoriasis.(10) 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 (ie, 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 noncontrolled observational studies on targeted UVB phototherapy.(11) This article was not limited to the 308-nm excimer laser as was the 2012 review, previously discussed.(8) 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.

Treatment-resistant psoriatic lesions

The findings of several small studies suggest that targeted phototherapy can be effective for treatment-resistant lesions. One patch comparison reported effective clearing (PASI pre 6.2, PASI post 1.0) of treatment-resistant psoriatic lesions; 6 of the patients had previously received topical treatment, 5 had received conventional phototherapy, and 3 had received combined treatments including phototherapy.(12) The same group reported that 12 of 13 subjects with “extensive and stubborn” scalp psoriasis (ie, unresponsive to class I topical steroids used in conjunction with tar and/or zinc pyrithione shampoos for at least 1 month) showed clearing following treatment with the 308-nm laser.(13) In an open trial from Europe, 44 of 54 patients with palmoplantar psoriasis resistant to combined phototherapy and systemic treatments were cleared of lesions with only 1 NB-UVB lamp treatment per week for 8 weeks.(14)

Section Summary

Several small RCTs and other small non-RCTs in patients with moderate to severe psoriasis have found that targeted phototherapy has efficacy similar to whole body phototherapy or PUVA. Targeted phototherapy is presumed to be safer or at least no riskier than whole body phototherapy. Several nonrandomized studies have found that targeted phototherapy can improve health outcomes in patients with treatment-resistant 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. (5) A 2012 industry-sponsored systematic review by Archier et al focused on studies comparing PUVA with NB-UVB in patients with chronic plaque psoriasis.(15) 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 addition, significantly more patients remained cleared at 6 months with PUVA compared with NB-UVB (OR=2.73; 95% CI, 1.18 to 6.27).

A 2013 systematic review by Almutawa et al identified 8 RCTs that evaluated oral PUVA and reporting PASI-75 as an outcome measure.(16) The mean percentage of patients achieving PASI-75 was 73% (95% CI, 56% to 88%). The mean clearance rate in 10 trials of PUVA monotherapy was 79% (95% CI, 68% to 88%). In 4 trials with bath PUVA monotherapy, the mean proportion of patients achieving PASI-75 was 47% (95% CI, 30% to 65%). The authors did not report outcomes in the control groups and thus conclusions cannot be drawn from this analysis on the relative efficacy of PUVA and other psoriasis treatments. A Cochrane review was published in 2013 on light therapy for psoriasis.(17) However, that review is less useful for the analysis at hand because the authors combined results of studies using PUVA and BB-UVB, rather than reporting outcomes separately for these 2 treatment modalities.

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.(18) 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 (9/44, 20.5%) than in the PUVA group (3/44, 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.(19) 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.(20) 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 assigned 60 patients with chronic plaque psoriasis to receive twice weekly PUVA ($n=30$) or twice weekly NB-UVB phototherapy ($n=30$). (21) 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.

Section Summary

RCTs and systematic reviews of RCTs have found that PUVA is at least as effective as NB-UVB in patients with moderate to severe psoriasis.

Home treatment

No studies were identified that compared home-based PUVA with office-based PUVA. A 2010 review of various types of home phototherapies for psoriasis did not discuss any studies on PUVA delivered at home.(22)

Summary

Targeted phototherapy describes the use of ultraviolet light that can be focused on specific body areas or lesions. The literature supports the use of targeted phototherapy for the treatment of moderate to severe psoriasis comprising less than 20% body area for which narrowband ultraviolet B (NB-UVB) or photochemotherapy with psoralen plus ultraviolet A (PUVA) are indicated, and for the treatment of mild to moderate localized psoriasis that is unresponsive to conservative treatment. Based on this review,

evidence is lacking for the use of targeted phototherapy for the first-line treatment of mild psoriasis or for the treatment of generalized psoriasis or psoriatic arthritis.

Evidence from randomized controlled trials suggests that PUVA is at least as effective as NB-UVB for patients with moderate to severe psoriasis. In addition, PUVA for severe treatment-resistant psoriasis is well-accepted and is recommended by the American Academy of Dermatology. There is a lack of evidence that home-based PUVA for treating psoriasis is as safe or effective as office-based treatment.

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.

Medicare National Coverage

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

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Eczema

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Billing Coding/Physician Documentation Information

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| 96900 | Actinotherapy (ultraviolet light) |
| 96912 | Photochemotherapy; psoralens and ultraviolet A (PUVA) |
| 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) |
| 96920 | Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm |
| 96921 | Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm |
| 96922 | Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm |

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 less than 250 sq cm, 250 sq cm-500 sq cm, over 500 sq cm).

The laser treatment codes are distinct from codes that describe the dermatological use of ultraviolet light, also known as actinotherapy (96900), and photochemotherapy (96910-96913).

Additional Policy Key Words

N/A

Policy Implementation/Update Information

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| 5/1/06 | New policy <i>titled Xenon Chloride Excimer Laser Therapy for Phototherapeutic Treatment of Psoriasis</i> ; considered investigational. |
| 12/1/06 | Policy statement revised to include medically necessary indications. Policy title changed to <i>Targeted Phototherapy for Psoriasis</i> . |
| 5/1/07 | No policy statement changes. |
| 5/1/08 | Policy statement revised to include medically necessary indications for eczema. |
| 5/1/09 | No policy statement changes. |
| 5/1/10 | No policy statement changes. |
| 5/1/11 | No policy statement changes. |
| 5/1/12 | Scope of policy changed to include PUVA for psoriasis. Policy title changed to "Light Therapy for Psoriasis." 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. Archived Policy 2.01.07 – Psoralens with Ultraviolet A (PUVA) in Psoriasis |
| 5/1/13 | No policy statement changes. |
| 5/1/14 | No policy statement changes. |

State and Federal mandates and health plan contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. The medical policies contained herein are for informational purposes. The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents Blue KC and are solely responsible for diagnosis, treatment and medical advice. No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, photocopying, or otherwise, without permission from Blue KC.