I. POLICY

Ultraviolet Light B [UVB] phototherapy, Narrowband UVB, Laser UVB or Psoralen and Ultraviolet light A (PUVA) therapy may be considered medically necessary for patients who have one of the following diagnoses that are resistant to, or has not adequately responded to conservative treatment (i.e. topical corticosteroids, coal/tar preparations, and ultraviolet light):

- Atopic dermatitis/severe eczema
- Dyshidrotic eczema
- Lichen planus
- Morphea
- Mycosis fungoides (cutaneous T-cell lymphoma)
- Parapsoriasis
- Pityriasis Rosea (PR)
- Polymorphic light eruptions
- Pruritus of renal disease
- Psoriasis (severe, disabling)
- Vitiligo

308nm Excimer Laser and/or Lamp

308nm Excimer Laser and/or Lamp may be considered medically necessary for the treatment of localized vitiligo (i.e., comprising less than 20% body area).

308nm Excimer Laser and/or Lamp may be considered medically necessary for the treatment of localized psoriasis (i.e., comprising less than 20% body area) who have failed to adequately respond to 3 or more months of topical treatments, including at least 3 of the following:

- Anthralin;
- Corticosteroids (e.g., betamethasone dipropionate ointment and fluocinonide cream);
- Keratolytic agents (e.g., lactic acid, salicylic acid, and urea);
- Retinoids (e.g., tazarotene);
- Tar preparations; and/or
- Vitamin D derivatives (e.g., calcipotriene).
No more than 13 laser treatments per course and 3 courses per year are generally considered medically necessary. If the person fails to respond to an initial course of laser therapy, as documented by a reduction in Psoriasis Area and Severity Index (PASI) score or other objective response measurement, additional courses are not considered medically necessary.

Laser treatment of acne scarring is considered cosmetic and not medically necessary.

**Goeckerman therapy**

Goeckerman therapy may be medically necessary in the treatment of:

- Atopic dermatitis/severe eczema
- Dyshidrotic eczema
- Psoriasis

**Targeted Phototherapy**

Targeted phototherapy may be considered medically necessary for the treatment of the following:

- Moderate to severe localized psoriasis (i.e., comprising less than 20% body area) for which NB-UVB or PUVA are indicated.
- Mild to moderate localized psoriasis that is unresponsive to conservative treatment.

Targeted phototherapy is considered investigational for the following as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure for these indications.

- First-line treatment of mild psoriasis
- Treatment of generalized psoriasis or psoriatic arthritis.
- Treatment of vitiligo

**Home Phototherapy**

Broad Band (BB) or Narrow Band (NB) UVB home phototherapy, may be considered medically necessary when all of the following criteria are met:

- Has an eligible diagnosis with documented positive response to UVL after at least six (6) months of treatment, and whose skin condition is chronic in nature and requires ongoing UVL therapy into the foreseeable future
- Device is approved by the FDA and appropriate for the body surface area being treated

All other uses of the lasers and lights not listed above as medically necessary are considered investigational as there is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with the procedure.
Policy Guidelines

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, 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. 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 6–10 office visits; treatment of recalcitrant lesions may involve around 24–30 office visits. Maintenance therapy or repeat courses of treatment may be required.

Cross-reference:
MP-4.018 Dermatologic Applications of Photodynamic Therapy

II. PRODUCT VARIATIONS

This policy is applicable to all programs and products administered by Capital BlueCross unless otherwise indicated below.

FEP PPO* BlueJourney HMO* BlueJourney PPO*

* The FEP program dictates that all drugs, devices or biological products approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational. Therefore, FDA-approved drugs, devices or biological products may be assessed on the basis of medical necessity. For Psoralens with Ultraviolet A, refer to FEP Medical Policy Manual MP-2.01.07 Psoralens with Ultraviolet A (PUVA). For targeted phototherapy for psoriasis refer to MP 2.01.47. For Light therapy for vitiligo, refer to MP-2.01.86 Light Therapy for Vitiligo. The FEP Medical Policy manual can be found at: www.fepblue.org

** Refer to the Centers for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD), 250.1 Treatment of Psoriasis for the current national coverage for the treatment of psoriasis.
Light therapy for psoriasis and vitiligo 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.

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 such celiac disease and Crohn disease. 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, pruritus) and impact on quality of life are also taken into account.\(^1\)\(^3\)

Topical therapy (e.g., corticosteroids, vitamin D analogs) is generally considered to be first-line treatment 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 (BB)-UVB devices, narrowband (NB)-UVB devices and psoralen plus ultraviolet A (PUVA). This policy addresses 2 treatments: PUVA and targeted phototherapy, i.e., use of ultraviolet light that can be focused on specific body areas or lesions.

Psoralen Plus Ultraviolet A

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 furcoumarins 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 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) 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 disease.

**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 (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 (lambda 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 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. 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% to 20% 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. A variety of topical agents are available including steroids, coal tar, vitamin D analogs (e.g., calcipotriol, calcitriol), tazarotene, anthralin.

**Regulatory Status**

In 2001, an XeCl excimer laser (XTRAC™ by PhotoMedex) received 510(k) clearance from 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 (e.g., the 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 Co., Bryan, OH previously manufactured by Lerner Medical Devices, Los Angeles, CA) was cleared by FDA 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 e.g., Oxsoralen (Valeant Pharmaceuticals).

**Vitiligo**

Vitiligo is an idiopathic skin disorder that causes depigmentation of sections of skin, most commonly on the extremities. Depigmentation occurs because melanocytes are no longer able to function properly. The cause of vitiligo is unknown; it is sometimes considered to be an autoimmune disease. The most common form of the disorder is non-segmental vitiligo (NSV) in which depigmentation is generalized, bilateral, symmetrical, and increases in size over time. In contrast, segmental vitililgo (SV), also called asymmetric or focal vitiligo, covers a limited area of skin. The typical natural history of vitiligo involves stepwise progression with long periods in which the disease is static and relatively inactive, and relatively shorter periods in which areas of pigment loss increase.

There are numerous medical and surgical treatments aimed at decreasing disease progression and/or attaining repigmentation. Topical corticosteroids, alone or in combination with topical vitamin D3 analogs, is a common first-line treatment for vitiligo. Alternative first-line therapies include topical calcineurin inhibitors, systemic steroids, and topical antioxidants.

Treatment options for vitiligo recalcitrant to first-line therapy include, among others, psoralens with ultraviolet A and targeted light therapy. PUVA uses a psoralen derivative in conjunction with long wavelength ultraviolet A 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. With topical PUVA, UVA exposure is generally administered within 30 minutes of psoralen application.

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**Regulatory Status**

In 2001, a 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).

**IV. RATIONALE**

**Psoriasis**

Assessment of efficacy for therapeutic interventions involves a determination of whether the intervention improves health outcomes. The optimal study design for a therapeutic intervention is a randomized controlled trial (RCT) that includes clinically relevant measures of health outcomes. Nonrandomized comparative studies and uncontrolled studies can sometimes provide useful information on health outcomes, but are prone to biases such as selection bias (e.g., noncomparability of treatment groups) and observation bias (e.g., placebo effect).

**Targeted Phototherapy**

There are several systematic reviews of the literature on targeted phototherapy. Reviews differed in the type of study included and the comparison interventions. A 2013 systematic review by Almutawa et al considered only RCTs; psoralen plus ultraviolet A (PUVA) was the comparison intervention. 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 ultraviolet B (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 2006 study by Neumann et al in which 10 patients were treated with a NB-UVB lamp or cream PUVA. 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 (2007) conducted a left-to-right comparison of local NB-UVB versus PUVA paint (3 times/wk for 9 weeks) in a cohort of 25 patients. 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. The authors identified 3 prospective nonrandomized studies comparing the 308 nm excimer laser with NB-UVB; no studies comparing the excimer laser with broadband ultraviolet B (BB-UVB) or PUVA were identified. Among the 3 studies was a 2006 study by Goldinger et al that compared the excimer laser with full-body NB-UVB in 16 patients. At the end of 20 treatments, Psoriasis Area and Severity Index (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. A 2005 study by Kollner et al included 15 patients with stable plaque psoriasis. 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). 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, published in 2012, included noncontrolled observational studies on targeted UVB phototherapy. This article was not limited to the 308 nm excimer laser as was the 2012 review, previously discussed. 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 were effective for treating localized psoriasis and were safer than whole body phototherapy because uninvolved skin is spared. The review did not pool study findings and did not evaluate separately studies of different psoriasis severity.

A small 2014 sham-controlled RCT by Levin et al evaluated the Levia targeted NB-UVB device. Although the device can be used at home, in the trial, treatments were provided by experienced phototherapists in a clinical setting. The study included patients with bilateral plaque-type psoriasis who had symmetric target lesions 2 to 4 cm in diameter. The minimum target lesion score (TLS) was 6, indicating at least moderate severity. (TLS is a 12-point scale that incorporates erythema, lesion thickness, and scaling.) Patients received targeted phototherapy on a randomly selected side of the body and sham (visible light treatment) on the other side. Treatments were given 3 times weekly for 12 weeks. Seventeen (81%) of 21 randomized patients completed the study. The primary end point, percentage of lesions that were clear or almost clear (TLS ≤3) at week 12 did not differ significantly between groups. The end point was attained on 10 treated lesions and 7 sham lesions (p=0.118). Two of 3 prespecified
secondary end points significantly favored active treatment. The percentage improvement in TLS was 43% on the treated side and 29% on the sham side (p=0.043). In addition, 12 lesions in the treated group and 7 in the placebo group had at least 50% improvement, as measured by TLS (p=0.020). However, percentage improvement in pruritus visual analog scale score, 62% on the treated side and 27% on the sham side, did not differ significantly between groups. The study had a relatively high dropout rate but because patients served as their own controls, this is not likely to be a major source of bias.

**Treatment-Resistant Psoriatic Lesions**

Several small studies suggest that targeted phototherapy can be effective for treatment-resistant lesions. One patch comparison reported effective clearing (pre-PASI=6.2; post-PASI=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.\(^{13}\) The same investigator group reported that 12 of 13 patients 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.\(^{14}\) In a 2006 open trial from Europe, 44 (81%) of 54 patients with palmoplantar psoriasis resistant to combined phototherapy and systemic treatments were cleared of lesions with only 1 NB-UVB lamp treatment weekly for 8 weeks.\(^{15}\)

**Section Summary: Targeted Phototherapy**

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. One small sham controlled RCT evaluating a targeted NB-UVB device had mixed findings; the primary outcome was statistically nonsignificant.

**Psoralen Plus Ultraviolet A**

Several systematic reviews have been published. As previously noted, Almutawa et al (2015) 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.\(^{16}\) 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 reported PASI-75 as an outcome measure.\(^{17}\) 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 2013 Cochrane review assessed light therapy for psoriasis. 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 2014, El-Mofty et al in Egypt published an RCT comparing PUVA and BB-UVA in 61 patients with psoriasis affecting at least 30% body surface area. Patients in the BB-UVA group were further randomized to 1 of 2 fixed doses: 10 or 15 J/cm\(^2\) per session. A maximum of 48 treatment sessions were provided. Clinical outcomes were significantly better in the PUVA group than the BB-UVA groups. For example, complete clearance was obtained by 23 (77%) of 30 patients in the PUVA group, 5 (31%) of 16 patients in the 10 J/cm\(^2\) UVA group, and 5 (33%) of 15 patients in the 15 J/cm\(^2\) UVA group (p=0.020).

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. 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% body surface area. The study included 40 patients randomly assigned to receive PUVA (n=30) and or UVA plus placebo psoralens (n=10). After washout periods of 2 weeks for topical psoriasis medications and 4 weeks for phototherapy and systemic therapies, patients were treated 3 times weekly for 12 weeks. Twenty-eight patients (70%) completed the study, 21 in the PUVA group and 7 in the UVA plus placebo group. The primary outcome was a 75% or greater improvement in PASI 75 score. In an intention-to-treat analysis with the last observation carried forward to analysis at 12 weeks, 19 (63%) of 30 patients in the PUVA group and 0 (0%) of 10 patients in the UVA plus placebo group achieved PASI 75 (p<0.001). In the per protocol analysis, 18 (86%) of 21 patients in the PUVA group and 0 (0%) of 7 patients in the placebo group achieved PASI 75. There were no serious adverse effects. The trial found a dramatic treatment benefit with PUVA compared with UVA plus placebo; however, there was substantial dropout 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 more than 20% body surface area. Patients received treatment with NB-UVB or PUVA 3 times weekly. Treatment continued until more than 75% clearance was attained or for a maximum of 16 weeks. Forty-three (84%) of 51 patients completed the study. Marked improvement (>75% clearance) was seen in 17 (91%) of 21 study completers in the NB-UVB group and 18 (82%) of 22 completers 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 trial 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). 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, 1.39 in the PUVA group; mean, 1.61 in the NB-UVB group). The mean number of treatments to achieve clearance, however, was significantly greater in the NB-UVB group than in the PUVA group, 16.4 versus 12.7, respectively.

**Section Summary: Psoralen Plus Ultraviolet A**

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. A 2014 RCT found that PUVA was more effective than BB-UVA.

**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.

**Ongoing and Unpublished Clinical Trials**

A search of ClinicalTrials.gov in December 2015 did not identify any ongoing or unpublished trials that would likely influence this review.

**Summary of Evidence**

The evidence for targeted phototherapy in patients who have mild psoriasis is limited. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Based on this review, evidence is lacking for the use of targeted phototherapy for the first-line treatment of mild psoriasis. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for targeted phototherapy in patients who have moderate-to-severe psoriasis includes randomized controlled trials (RCTs) and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. The literature supports the use of targeted phototherapy for the treatment of moderate-to-severe psoriasis comprising less than 20% body surface area for which narrowband ultraviolet B 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. The evidence is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

The evidence for PUVA in patients who have moderate-to-severe psoriasis includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Evidence from RCTs suggests that office-based PUVA is at least as effective as narrowband ultraviolet B and broadband ultraviolet A 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. The evidence is
sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

**Practice Guidelines and Position Statements**

The American Academy of Dermatology 2010 guideline on the management of psoriasis recommended targeted phototherapy for patients with mild, moderate, or severe psoriasis with less than 10% involvement of the body surface area. Systemic PUVA with ultraviolet A is indicated in adults with generalized psoriasis who are 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. PUVA is addressed for treatment of intractable, disabling psoriasis, but only after the psoriasis has not responded to more conventional treatment.

**Vitiligo**

This evidence review was created in 2012 with a search of the MEDLINE database through March 6, 2013. It has been updated with a literature review through November 11, 2015. Following is a summary of the key literature published to date.

**Targeted Phototherapy**

In 2015, Whitton et al published an updated Cochrane review of randomized controlled trials (RCTs) on treatments for vitiligo. The investigators searched the literature through October 2013 and identified 12 trials on laser light devices. Six trials evaluated the combination of laser light devices and a topical therapy and 2 evaluated the combination of laser devices and surgical therapy. Three trials compared regimens of laser monotherapy. The remaining trial compared a helium neon laser and a 290 to 320 nm broadband ultraviolet B (UVB) fluorescent lamp. Due to heterogeneity across studies, the Cochrane authors did not pool study findings. In most trials, all groups received laser light treatment, alone or as part of combination therapy, and thus the effect of targeted phototherapy could not be isolated.

In 2015, Sun et al published a systematic review of RCTs that focused on treatment of vitiligo with the 308 nm excimer laser. Review authors identified 7 RCTs with a total of 390 patients. None of the studies were conducted in the United States; 5 were from Asia. Three of the trials compared the excimer laser with an excimer lamp, and 4 studies compared the excimer laser with narrowband ultraviolet B (NB-UVB). The 4 studies with the comparison with NB-UVB are of greatest interest to this review. However, 2 of these were not published in English, and 1 had a sample size of only 14 patients. The fourth study, published by Yang et al in 2010, did not report efficacy outcomes such as clinical response rate or repigmentation rate. Instead, the investigators reported on the proportion of patients with various types of repigmentation: perifollicular, marginal, diffuse, or combined. Repigmentation rates did not differ significantly between groups treated with the excimer laser versus NB-UVB. The authors of the systematic review conducted a meta-analysis of the 2 studies that were not published in English; thus,
results cannot be verified. They reported that the likelihood of a minimum 50% repigmentation rate was significantly higher with the excimer laser compared with NB-UVB (risk ratio, 1.39, 95% confidence interval [CI], 1.05 to 1.85). Review authors also stated that, in qualitative analysis, neither of these studies showed significant benefit of the excimer laser for achieving a minimum 75% repigmentation rate.

One of the few trials comparing laser therapy to an alternative treatment was published in 2012 by Nistico et al. This was a nonblinded RCT that included 53 patients with localized and generalized vitiligo. Patients were randomly assigned to 1 of 3 treatments for 12 weeks: (1) excimer laser plus vitamin E (n=20); (2) excimer laser plus topical 0.1% tacrolimus ointment and vitamin E (n=20); and (3) vitamin E only (control group, n=13). All patients in the 2 excimer laser groups completed treatment; 1 patient in the control group dropped out. Before and after treatment, 2 independent clinicians rated clinical response; 51% to 75% repigmentation was considered a “good” response and greater than 75% repigmentation was considered an “excellent” response. The proportion of patients with a good or excellent response was 11 (55%) of 20 in the laser plus vitamin E group, 14 (70%) of 20 in the laser plus tacrolimus plus vitamin E group, and 0 in the control group. The rate of good or excellent response did not differ significantly between the groups that received excimer laser therapy with and without topical treatment (p=0.36). The response rate was significantly better in both groups receiving laser treatment compared with the control group (p<0.001).

Section Summary: Targeted Phototherapy

There are a number of RCTs evaluating targeted phototherapy for treating vitiligo. However, studies tended to have small sample sizes, and few were designed to isolate the effect of laser therapy. Moreover, studies were heterogeneous e.g., different interventions or combinations of interventions and different comparison interventions. These characteristics make it difficult to pool study findings or to draw conclusions about the efficacy of targeted phototherapy for vitiligo.

Psoralens With Ultraviolet A

The 2015 Cochrane review of trials on treatments for vitiligo, previously discussed in the section on targeted phototherapy, identified 12 RCTs evaluating oral psoralens with ultraviolet A (PUVA). Four trials assessed oral PUVA alone, and 8 assessed PUVA in combination with other treatments, e.g., calcipotriol, azathioprine, polypodium leucotomos, khellin, or surgical treatment. Seven of the 8 studies used 9-methoxypsoralen. Due to differences across studies, results from trials of oral PUVA and of oral PUVA plus sunlight were not pooled.

An earlier meta-analysis of treatments for vitiligo was published in 1998 by Njoo et al. A pooled analysis of 2 RCTs of oral unsubstituted psoralen plus sun for generalized vitiligo (total N=97) found a statistically significant treatment benefit of active treatment compared with placebo (pooled odds ratio [OR], 19.9; 95% CI, 2.4 to 166.3). A pooled analysis of 3 RCTs, 2 of oral methoxsalen plus sun and 1 of oral trioxsalen plus sun (total N=181) also found a significant benefit of active treatment versus placebo for generalized vitiligo (OR=3.8; 95% CI, 1.3 to 11.3). All studies were published before 1985, had relatively small sample sizes (confidence intervals were wide), and used sun exposure rather than artificial UVA.
In 2007, Yones et al published an RCT that used a psoralen formulation available in the United States. The trial enrolled 56 patients in the United Kingdom who had nonsegmental vitiligo. Outcome assessment was blinded. Patients were randomly assigned to receive twice-weekly treatments with methoxsalen hard gelatin capsules (8-MOP) psoralen plus UVA (n=28) or NB-UVB therapy (n=28). NB-UVB treatments were administered in a Waldmann UV500 cabinet containing 24 Phillips 100 NB-UVB fluorescent tubes. In the PUVA group, the starting dose of irradiation was 0.5 J/cm², followed by 0.25 J/cm² incremental increases if tolerated. Patients were evaluated after every 16 sessions and followed for up to 1 year. All patients were included in the analysis. The median number of treatments received was 49 in the PUVA group and 97 in the NB-UVB group. At the end of treatment, 16 (64%) of 25 patients in the NB-UVB group had greater than 50% improvement in body surface area affected compared with 9 (36%) of 25 patients in the PUVA group. In addition, 5 (20%) of 25 of patients in the PUVA group and 8 (32%) of 25 in the NB-UVB group had at least 75% improvement in the body surface area affected. Although the authors did not provide p values in their outcome table, they stated that the difference in improvement did not differ significantly between groups for the patient population as a whole. Among patients who received at least 48 treatments, improvement was significantly greater in the NB-UVB group (p=0.007). A total of 24 (96%) patients in the PUVA group and 17 (68%) in the NB-UVB group developed erythema at some point during treatment; this difference was statistically significant (p=0.02).

Section Summary: Psoralens With Ultraviolet A
There is some evidence from randomized studies, mainly those published before 1985, that PUVA is more effective than placebo for treating vitiligo. The limited number of studies comparing PUVA with NB-UVB have had mixed findings.

Ongoing and Unpublished Clinical Trials
A search of ClinicalTrials.gov in December 2015 did not identify any ongoing or unpublished trials that would likely influence this review.

Summary of Evidence
The evidence for targeted phototherapy in patients who have vitiligo includes randomized controlled trials (RCTs). Relevant outcomes are change in disease status, quality of life, and treatment-related morbidity. The studies tend to have small sample sizes, and few were designed to isolate the effect of laser therapy. There is a lack of clinical trial evidence that compares this technique with more conservative treatments or no treatment/placebo. The evidence is insufficient to determine the effects of the technology on health outcomes.

The evidence for psoralen plus ultraviolet A (PUVA) in patients who have vitiligo includes RCTs. Relevant outcomes are change in disease status, quality of life, and treatment-related morbidity. There is some evidence from randomized studies, mainly those published before 1985, that PUVA is more effective than placebo for treating vitiligo. PUVA for vitiligo is recommended in British guidelines for adults who do not respond to more conservative treatments. Based on the available evidence and clinical guidelines, PUVA may be considered in patients with vitiligo who have not responded adequately to conservative therapy. The evidence
is sufficient to determine qualitatively that the technology results in a meaningful improvement in the net health outcome.

Practice Guidelines and Position Statements

**British Association of Dermatologists et al**
In 2008, a guideline on the diagnosis and management of vitiligo was published by several organizations in the U.K. including the British Association of Dermatologists, the Royal College of Physicians of London, and the Cochrane Skin Group. The guideline included the following statements:

- PUVA therapy should be considered for treatment of vitiligo only in adults who cannot be adequately managed with more conservative treatments. PUVA is not recommended in children. (Grade of recommendation D, Level of evidence 4)
- If phototherapy is to be used for treating nonsegmental vitiligo, NB-UVB should usually be used in preference to oral PUVA. (Grade of recommendation A, Level of evidence 1+)
- A trial of PUVA therapy should be considered only for adults with widespread vitiligo, or localized vitiligo associated with a significant impact on patient's quality of life. Ideally, this treatment should be reserved for patients with darker skin types. (Grade of recommendation D, Level of evidence 3)
- Before starting PUVA treatment, patients should be made aware that there is no evidence that this treatment alters the natural history of vitiligo. They should also be made aware that not all patients respond, and that some sites on the body, such as the hands and feet, respond poorly in all patients. They should also be informed of the limit to the number of treatments due to possible adverse effects. (Grade of recommendation D, Level of evidence 3)

**European Dermatology Forum**
In 2013, the European Dermatology Forum published consensus guidelines on the management of vitiligo. The guidelines stated that oral PUVA is commonly used in adults with generalized vitiligo as second-line treatment. The guideline also stated that targeted phototherapy is indicated for localized vitiligo, particularly small lesions of recent onset and childhood vitiligo, to avoid adverse effects due to total body irradiation and when total body irradiation is contraindicated. The guidelines were based on expert opinion and not on a systematic review of the literature.

**U.S. Preventive Services Task Force Recommendation**
Not applicable.

**Medicare National Coverage**
There is no national coverage determination (NCD).
V. DEFINITIONS

510 (k) A premarketing submission made to FDA to demonstrate that the device to be marketed is as safe and effective, that is, substantially equivalent (SE), to a legally marketed device that is not subject to premarket approval (PMA). Applicants must compare their 510(k) device to one or more similar devices currently on the U.S. market and make and support their substantial equivalency claims.

Dermatitis is an inflammatory rash marked by itching and redness.

Eczema is an itchy red rash that initially oozes serum and may become crusted, thickened or scaly. Eczematous rash may result from various causes, including allergies, irritating chemicals, drugs, or sun exposure. It may be acute or chronic.

Goeckerman Therapy a regimen that consists of exposure to ultraviolet B (UVB) light and application of crude coal tar (CCT)

Laser Ultraviolet Light Blue (UVB) a special type of laser (i.e., narrow band) used to deliver UVB light in the specific range between 310-312 nm.

Light Therapy for Psoriasis includes both targeted phototherapy and photochemotherapy with psoralin plus ultraviolet A (PUVA).

Leukoderma refers to deficiency of skin pigmentation.

Phototherapy refers to the treatment of disorders by the use of light, especially ultraviolet light.

Pityriasis Rosea refers to a mild exanthematous inflammation of unknown etiology. It is characterized by the presence of salmon-colored maculopapular lesions. The eruptions are usually generalized, affecting chiefly the trunk, and the course is often self-limiting.

Pruritus is a tingling or faintly burning skin sensation that prompts a person to rub or scratch.

Psoralen refers to a group of substances derived from plants, which are capable of causing a phototoxic dermatitis when applied to the skin and exposed to sunlight or artificial ultraviolet wavelengths.

Psoriasis is a common, chronic disease of the skin that consists of reddened papules that develop to form plaques with distinct borders. As the disease progresses and if it is untreated, a silvery, yellow-white scale develops. New lesions tend to appear at sites of trauma, but frequently are located on the scalp, knees, elbows, and genitalia.

PUVA uses a psoralen derivative in conjunction with long wavelength ultraviolet A (UVA) light (sunlight or artificial) for photochemotherapy of skin conditions.

Targeted phototherapy describes the use of ultraviolet light that can be focused on specific body areas or lesions. It involves application of light energy directly focused on, the lesion through special delivery mechanisms such as fiber-optic cables. It includes different technologies.
such as excimer laser, intense pulse light systems, and UV light sources with hand-held delivery systems.

**ULTRAVIOLET B (UVB)** is one of the three types of invisible light rays (together with ultraviolet A and ultraviolet C) given off by the sun.

**VITILIGO** is a skin disorder characterized by a patchy loss of skin pigment. The depigmented areas, which appear most commonly on the hands, face and genital regions, are flat and pale and surrounded by normal pigmentation.

### VI. BENEFIT VARIATIONS

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member’s individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member’s benefit information or contact Capital for benefit information.

### VII. DISCLAIMER

"Capital’s medical policies are developed to assist in administering a member’s benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member’s benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law."

### VIII. CODING INFORMATION

**Note:** This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

**Covered when medically necessary:**

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<tr>
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<th>Description</th>
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<tr>
<td>E0691</td>
<td>Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 sq ft or less</td>
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<td>E0692</td>
<td>Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 ft panel</td>
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<td>E0693</td>
<td>Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 ft panel</td>
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<td>E0694</td>
<td>Ultraviolet multidirectional light therapy system in 6 ft cabinet, includes bulbs/lamps, timer, and eye protection</td>
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<td>E1399</td>
<td>Durable medical equipment, miscellaneous</td>
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<td>S9098</td>
<td>Home visit, phototherapy services (e.g., Bili-lite), including equipment rental, nursing services, blood draw, supplies, and other services, per diem</td>
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<td>C84.03</td>
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<td>ICD-10-CM Diagnosis Codes</td>
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*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

**IX. REFERENCES**

Psoriasis


**Vitiligo**


**Other Sources:**


### X. Policy History

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<td>Deleted statement related to coverage limitation for home phototherapy units. Added new investigational statement indicating targeted phototherapy is considered <strong>investigational</strong> for the treatment of vitiligo. Now silent on specific FDA information regarding Oxsoralen.</td>
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<td>Minor review. Added indications for Excimer laser and lamp. Morphea added as an indication for UVB therapy. Coding reviewed added diagnoses for Morphea.</td>
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*Health care benefit programs issued or administered by Capital BlueCross and/or its subsidiaries, Capital Advantage Insurance Company®, Capital Advantage Assurance Company® and Keystone Health Plan® Central. Independent licensees of the BlueCross BlueShield Association. Communications issued by Capital BlueCross in its capacity as administrator of programs and provider relations for all companies.*