

**MEDICAL POLICY**

<b>POLICY TITLE</b>	<b>ULTRAVIOLET LIGHT THERAPIES</b>
<b>POLICY NUMBER</b>	<b>MP-2.046</b>

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**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).

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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.

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**Policy Guidelines**

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

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

During psoralen plus ultraviolet A therapy, the patient with vitiligo or psoriasis 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, psoralen plus ultraviolet A is generally not recommended for home therapy.

*Cross-reference:*

**MP-4.018** Dermatologic Applications of Photodynamic Therapy

**II. PRODUCT VARIATIONS**

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

FEP 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](http://www.fepblue.org)

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**III. DESCRIPTION/BACKGROUND**

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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 (eg, celiac disease, Crohn disease). Although disease severity is minimally defined by body surface area (mild psoriasis affects <5% of body surface area, moderate psoriasis affects 5%-10%, and severe disease affects >10% of 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.<sup>1-3</sup>

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

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 an autoimmune disease. The most common form of the disorder is nonsegmental vitiligo in which depigmentation is generalized, bilateral, symmetrical, and increases in size over time. In contrast, segmental vitiligo, 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

**PSORIASIS**

**Treatment**

Topical therapy (eg, corticosteroids, vitamin D analogues) is generally considered first-line treatments of psoriasis, especially for mild disease. Phototherapy and systemic therapy are treatment options for patients with more extensive and/or severe disease and those who fail conservative treatment with topical agents. Phototherapy is available in various forms including exposure to natural sunlight, use of broadband ultraviolet B (BB-UVB) devices, narrowband ultraviolet B (NB-UVB) devices, targeted phototherapy, and psoralen plus ultraviolet A (PUVA). NB-UVB is an established treatment for psoriasis, based on efficacy and safety. This evidence review addresses 2 alternative treatments: targeted phototherapy, which uses ultraviolet light that can be focused on specific body areas or lesions, and PUVA.

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***Targeted Phototherapy***

Potential advantages of targeted phototherapy include the ability to use higher treatment doses and to limit exposure to surrounding tissue. BB-UVB devices, which emit wavelengths from 290 to 320 nm, have been largely replaced by NB-UVB devices. NB-UVB devices eliminate wavelengths below 296 nm, which are considered erythemogenic and carcinogenic but not therapeutic. NB-UVB is more effective than 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, an excimer (excited dimer) laser using xenon chloride (XeCl) and lamps were developed as targeted NB-UVB treatment devices; they generate monochromatic or very narrow band radiation with a lambda max of 308 nm. Targeted phototherapy devices are directed at specific lesions or affected areas, thus limiting exposure to the surrounding normal tissues. They may, therefore, allow higher dosages compared with a light box, which could result in fewer treatments to produce clearing. The original indication of the excimer laser was for patients with mild-to-moderate psoriasis, defined as involvement of less than 10% of the skin. Newer XeCl laser devices are faster and more powerful than the original models, which may allow treatment of patients with more extensive skin involvement (10%-20% body surface area).

***Psoralen Plus Ultraviolet A***

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

PUVA has most commonly been used to treat severe psoriasis, for which there is no generally accepted first-line treatment. Each treatment option (eg, 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; they generally can be managed by altering the dose of psoralen or ultraviolet light. Potential long-term effects include photoaging and skin cancer, particularly squamous cell carcinoma and possibly malignant melanoma. PUVA is generally considered more effective than targeted phototherapy for the treatment of psoriasis. However, the requirement of systemic exposure and the higher risk of adverse reactions (including a higher carcinogenic risk) have generally limited PUVA therapy to patients with more severe disease.

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**REGULATORY STATUS**

In 2001, XTRAC™ (PhotoMedex, Willow Grove, PA), an XeCl excimer laser, was cleared for marketing by FDA through the 510(k) process for the treatment of mild-to-moderate psoriasis. The 510(k) clearance was subsequently obtained for a number of targeted UVB lamps and lasers, including newer versions of the XTRAC system (eg, XTRAC Ultra™), the VTRAC™ lamp (PhotoMedex), the BClear™ lamp (Lumenis, Israel), and the European manufactured Excilite™ and Excilite μ™ XeCl lamps. FDA product code: FTC.

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

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

**Vitiligo**

**Treatment**

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 D<sub>3</sub> analogues, are common first-line treatments 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, light box therapy with narrow-band ultraviolet B (NB-UVB) and psoralen plus ultraviolet A (PUVA).

Targeted phototherapy with handheld lamps or lasers is also being evaluated. Potential advantages of targeted phototherapy include the ability to use higher treatment doses and to limit exposure to surrounding tissue. Original UVB devices consisted of a Phillips TL-01 fluorescent bulb with a maximum wavelength (lambda max) of 311 nm. Subsequently, xenon chloride lasers and lamps were developed as targeted UVB treatment devices; they generate monochromatic or very narrowband 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.

PUVA uses a psoralen derivative in conjunction with long wavelength ultraviolet A (UVA) light (sunlight or artificial) for photochemotherapy of skin conditions. Psoralens are tricyclic 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 the direct application of 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, XTRAC™ (PhotoMedex), a xenon chloride (XeCl) excimer laser, was cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for the treatment of skin conditions such as 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), the 308 excimer lamp phototherapy system (Quantel Medical), MultiClear Multiwavelength Targeted Phototherapy System, Psoria-Light™, and the Excilite™ and Excilite μ™ XeCl lamps. The intended use of all of these devices includes vitiligo among other dermatologic indications. Some light-emitting devices are handheld. FDA product code: GEX.

The oral psoralen products Oxsoresalen-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 (eg, Oxsoresalen® [Valeant]).

**IV. RATIONALE**

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**Psoriasis**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The most appropriate comparator for targeted therapy is narrowband ultraviolet B (NB-UVB), which is an established treatment for psoriasis and can be administered in the home. The efficacy

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of psoralen plus ultraviolet A (PUVA) has been compared with NB-UVB, which has fewer side effects, or with ultraviolet A (UVA) with placebo.

**TARGETED PHOTOTHERAPY****Mild Localized Psoriasis**

The original indication of the excimer laser was mild-to-moderate psoriasis, defined as involvement of less than 10% of the skin. Typically, this patient population has not been considered for light box therapy, because the risks of exposing the entire skin to the carcinogenic effects of ultraviolet B (UVB) light may outweigh the benefits of treating a small number of lesions. The American Academy of Dermatology does not recommend phototherapy for patients with mild localized psoriasis whose disease can be controlled with topical medications, including steroids, coal tar, vitamin D analogues (eg, calcipotriol, calcitriol), tazarotene, and anthralin.<sup>4</sup>

**Section Summary: Mild Localized Psoriasis**

There is no evidence and no clinical recommendation for targeted phototherapy to treat patients with mild localized psoriasis whose disease can be controlled with topical medications.

**Treatment-Resistant Mild Psoriasis**

Several small studies have suggested that targeted phototherapy can be effective for treatment-resistant lesions. One 2003 patch comparison reported effective clearing (pre Psoriasis Area and Severity Index [PASI] score, 6.2; post-PASI score, 1.0) of treatment-resistant psoriatic lesions; six of the patients had previously received topical treatment, five had received conventional phototherapy, and three had received combined treatments including phototherapy.<sup>5</sup> In 2004, the same investigator group reported that 12 of 13 patients with “extensive and stubborn” scalp psoriasis (i.e., 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.<sup>6</sup> 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 a single NB-UVB lamp treatment weekly for 8 weeks.<sup>7</sup>

**Section Summary: Treatment-Resistant Mild Psoriasis**

Several nonrandomized studies have found that targeted phototherapy can improve health outcomes in patients with treatment-resistant psoriasis.

**Moderate-to-Severe Localized Psoriasis**

There are several systematic reviews of the literature on targeted phototherapy. Reviews differed in the type of study selected and the comparison interventions. A 2015 systematic review by Almutawa et al considered only RCTs; PUVA was the comparison intervention.<sup>8</sup> Reviewers identified 3 RCTs comparing the efficacy of targeted UVB phototherapy with PUVA for treatment of plaque psoriasis. Two of the 3 trials used an excimer laser (308 nm) as the source of targeted phototherapy, and the third used localized NB-UVB light. There was no statistically significant difference between the 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).



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In 2012, Mudigonda et al published a systematic review of controlled studies (RCTs and non-RCTs) on targeted vs nontargeted phototherapy for patients with localized psoriasis.<sup>9</sup> Reviewers identified 3 prospective nonrandomized studies comparing the 308-nm excimer laser with NB-UVB. Among these studies was a 2006 study by Goldinger et al that compared the excimer laser with full-body NB-UVB in 16 patients.<sup>10</sup> At the end of 20 treatments, 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.<sup>11</sup> 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 differences in the efficacy of the 3 treatments after 10 weeks. The mean number of treatments to achieve clearance of lesions was 24.

***Section Summary: Moderate-to-Severe Localized Psoriasis***

Systematic reviews of small RCTs and non-RCTs in patients with moderate-to-severe psoriasis have found that targeted phototherapy has efficacy similar to whole body phototherapy or PUVA. Targeted phototherapy is presumed to be safer or at least no riskier than whole body phototherapy, due to risks of exposing the entire skin to the carcinogenic effects of UVB light.

**PSORALEN PLUS ULTRAVIOLET A**

A number of RCTs and systematic reviews of RCTs have compared PUVA with other light therapies or with placebo. A 2013 Cochrane review assessed light therapy for psoriasis.<sup>12</sup> However, that review is less useful for this evidence evaluation because reviewers combined results of studies using PUVA and broadband (BB) UVB, rather than reporting outcomes separately for these treatment modalities.

**PUVA vs NB-UVB**

A 2012 industry-sponsored systematic review by Archier et al focused on studies comparing PUVA to NB-UVB in patients with chronic plaque psoriasis.<sup>13</sup> Pooled analysis of 3 RCTs found a significantly higher psoriasis clearance with PUVA than 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 than with NB-UVB (OR=2.73; 95% CI, 1.18 to 6.27).

**PUVA vs Topical Steroids**

In 2012, Amirnia et al published a trial in which 88 patients with moderate plaque psoriasis were randomized to PUVA or topical steroids.<sup>14</sup> 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) was reported significantly more often in the topical steroid group (9/44 [20.5%]) than in the PUVA group (3/44 [6.8%]; p=0.007).

**PUVA vs UVA Without Psoralens**

In 2014, El-Mofty et al published an RCT comparing PUVA with BB-UVA in 61 patients with psoriasis affecting at least 30% body surface area.<sup>15</sup> Clinical outcomes were significantly better

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in the PUVA group than in 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<sup>2</sup> UVA group, and 5 (33%) of 15 patients in the 15 J/cm<sup>2</sup> UVA group (p=0.020).

In 2009, Sivanesan et al published a double-blind RCT evaluating the efficacy of 8-methoxypsoralen PUVA treatment in patients with moderate-to-severe psoriasis affecting at least 10% body surface area.<sup>16</sup> The trial included 40 patients randomized to PUVA (n=30) and or UVA plus placebo psoralens (n=10). Patients were treated 3 times weekly for 12 weeks. The primary outcome was a 75% or greater improvement in PASI 75 score. 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 the primary outcome measure (p<0.001). There were no serious adverse effects.

**Section Summary: Psoralen Plus Ultraviolet A**

RCTs and systematic reviews of RCTs have found that PUVA is more effective than NB-UVB, topical steroids, or UVA without psoralens in patients with moderate-to-severe psoriasis. Due to side effects, PUVA is typically restricted to more severe cases.

**SUMMARY OF EVIDENCE**

For individuals who have mild localized psoriasis who receive targeted phototherapy, there is little evidence. Relevant outcomes are symptoms, change in disease status, quality of life, and treatment-related morbidity. Evidence is lacking on the use of targeted phototherapy as first-line treatment of mild psoriasis. The evidence is insufficient to determine the effects of the technology on health outcomes.

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

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

For individuals who have generalized psoriasis who receive PUVA, the evidence includes RCTs and systematic reviews. Relevant outcomes are symptoms, change in disease status, quality of

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life, and treatment-related morbidity. RCTs and systematic reviews of RCTs have found that PUVA is more effective than narrowband UVB, topical steroids, or UVA without psoralens in patients with generalized psoriasis. The evidence is sufficient to determine that the technology results in a meaningful improvement in the net health outcome.

**PRACTICE GUIDELINES AND POSITION STATEMENTS**

**American Academy of Dermatology**

The American Academy of Dermatology 2010 guidelines on the management of psoriasis recommended that patients with psoriasis who are compliant could, under dermatologist supervision, be considered appropriate candidates for home ultraviolet B therapy.<sup>4</sup> Targeted phototherapy was recommended for patients with mild, moderate, or severe psoriasis with less than 10% involvement of the body surface area. Systemic psoralen plus ultraviolet A was indicated in adults with generalized psoriasis resistant to topical therapy.

**National Psoriasis Foundation**

In 2017, the National Psoriasis Foundation published a consensus guidance based on a task force review of the literature on the treatment for psoriasis involving skinfolds (inverse or intertriginous) psoriasis.<sup>17</sup> The treatment guidance for intertriginous or genital psoriasis stated: "...there is anecdotal evidence demonstrating the strong clinical efficacy of biologic treatment; with limited knowledge on the effects of biologics on intertriginous or genital psoriasis." The guidance on inverse psoriasis is provided in Table 1.

**Table 1. Recommendations on Treatment of Inverse Psoriasis**

<b>Line of Therapy</b>	<b>Recommendation</b>
First-line therapy	Low potency topical steroids for periods less than 2-4 wk Other topical therapies to consider are tacrolimus, pimecrolimus, calcitriol, or calcipotriene to avoid steroid side effects with long-term treatment
Second- and third-line therapies	Antimicrobial therapy, emollients, and tar-based products Axillary involvement can be treated with botulinum toxin injection to reduce perspiration and inhibit inflammatory substance release Excimer laser therapy or systemic agents

In 2017, the National Psoriasis Foundation also published recommendations based on a review of the literature on the treatment for psoriasis in solid organ transplant patients.<sup>18</sup> Because organ transplant patients are excluded from randomized controlled trials, there are limited data. The recommendations were based on case series (see Table 2).

**Table 2. Recommendations on Treatment of Psoriasis for Solid Organ Transplant Patients**

<b>Line of Therapy</b>	<b>Recommendation</b>
First-line therapy for mild-to-moderate psoriasis	Topical therapy
First-line therapy for moderate-to-severe psoriasis	<ul style="list-style-type: none"> <li>• Acitretin with narrowband ultraviolet light or</li> <li>• Narrowband ultraviolet light or</li> <li>• Acitretin</li> </ul>
Second-line therapy	Increasing the current anti-rejection drug dose
Severe psoriasis or refractory cases	Systemic or biologic therapies

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**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS**

Not applicable.

**MEDICARE NATIONAL COVERAGE**

Ultraviolet light treatment is covered; targeted phototherapy is not specifically mentioned. There is no national coverage determination on psoralen plus ultraviolet A.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**

Some currently unpublished trials that might influence this review are listed in Table 3.

**Table 3. Summary of Key Trials**

<b>NCT No.</b>	<b>Trial Name</b>	<b>Planned Enrollment</b>	<b>Completion Date</b>
<b>Ongoing</b>			
NCT02294981	Excimer Laser Phototherapy Outcomes in the Treatment of Psoriasis (Photos)	30	Jun 2017 (ongoing)
NCT03180866 <sup>a</sup>	Evaluation of Efficacy, Duration of Remission and Safety of a Light and Occlusive Patch Therapy for Plaque Psoriasis	30	Mar 2018
NCT02999776 <sup>a</sup>	Laser-assisted Topical Administration of Etanercept (Enbrel®) in Patients With Mild to Moderate Plaque-type Psoriasis	30	Jun 2018

NCT: national clinical trial.

<sup>a</sup> Denotes industry-sponsored or cosponsored trial.

**Vitiligo**

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

The most appropriate comparison for targeted phototherapy and oral psoralens with ultraviolet A (PUVA) is narrowband ultraviolet B (NB-UVB), which is considered a standard treatment for

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active and/or widespread vitiligo based on efficacy and safety. The following is a summary of the key literature published to date.

**TARGETED PHOTOTHERAPY**

**Systematic Reviews**

In 2015, Whitton et al updated a Cochrane review of RCTs on treatments for vitiligo.<sup>1</sup> The literature search, conducted through October 2013, identified 12 trials on laser light devices: 6 trials evaluated the combination of laser light devices and a topical therapy; 2 evaluated the combination of laser devices and surgical therapy; 3 compared regimens of laser monotherapy; and 1 compared a helium neon laser with a 290- to 320-nm broadband UVB fluorescent lamp. Due to heterogeneity across studies, reviewers 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. Adverse event reports across the studies included burning, stinging, moderate-to-severe erythema, itching, blistering, and edema.

In 2015, Sun et al published a systematic review of RCTs that focused on the treatment of vitiligo with the 308-nm excimer laser.<sup>2</sup> In a literature search conducted through April 2014, reviewers identified 7 RCTs (total N=390 patients) for inclusion. None of the studies was conducted in the United States; five were from Asia and three of those five are available only in Chinese. Three trials compared the excimer laser with an excimer lamp, and four compared the excimer laser with NB-UVB. One trial had a sample size of only 14 patients and another, published by Yang et al (2010),<sup>3</sup> did not report repigmentation rates, providing instead, the proportion of patients with various types of repigmentation (perifollicular, marginal, diffuse, or combined). Repigmentation rates at the 75% and 100% level did not differ significantly between groups treated with the excimer laser vs NB-UVB. Reviewers conducted a meta-analysis of the 2 studies not published in English, though results cannot be verified. Results showed that the likelihood of 50% or more repigmentation was significantly higher with the excimer laser than with NB-UVB (relative risk [RR], 1.39, 95% confidence interval [CI], 1.05 to 1.85). Two of the 4 studies discussed adverse events, with itching and burning reported by both treatment and control groups and erythema and blistering reported only by the patient in the laser group.

A 2016 systematic review by Lopes et al identified 3 studies that compared targeted phototherapy using a 308-nm excimer lamp with NB-UVB (315 patients, 352 lesions) and 3 studies that compared the excimer lamp with the excimer laser (96 patients, 412 lesions).<sup>4</sup> No differences between the excimer lamp and NB-UVB were identified for the outcome of 50% or more repigmentation (RR=1.14; 95% CI, 0.88 to 1.48). For repigmentation of 75% or more, only 2 small studies were identified, and they showed a lack of precision in the estimate (RR=1.81; 95% CI, 0.11 to 29.52). For the 3 studies that compared the excimer lamp with the excimer laser, there were no significant differences at the 50% or more repigmentation level (RR=0.97; 95% CI, 0.84 to 1.11) or the 75% or more repigmentation level (RR=0.96; 95% CI, 0.71 to 1.30). All treatments were most effective in lesions located on the face, with the worst response being lesions on the extremities. There was some evidence of an increase in adverse events such as blistering with targeted phototherapy.

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**Randomized Controlled Trials**

An RCT comparing laser with an alternative treatment was published in 2012 by Nistico et al.<sup>5</sup> This nonblinded RCT included 53 patients with localized and generalized vitiligo. Patients were randomized to 1 of 3 treatments for 12 weeks: (1) excimer laser plus vitamin E (n=20); (2) excimer laser plus topical tacrolimus ointment 0.1% 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 75% or more 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 responses did not differ significantly between groups that received excimer laser therapy with and without topical treatment (p=0.36). Response rates were significantly better in both groups receiving laser treatment than in the control group (p<0.001).

In 2017, Zhang et al published an RCT evaluating the use of the 308-nm targeted laser with and without Yiqiqubai granule for the treatment of vitiligo.<sup>6</sup> Yiqiqubai granule is a therapy in traditional Chinese medicine, which is believed to activate blood circulation. The trial had 3 arms: 75 patients received twice- daily oral Yiqiqubai alone, 78 received weekly laser treatments alone, and 80 received both twice-daily oral Yiqiqubai and weekly laser treatments. All groups received treatment for 6 months. Two dermatologists not involved in the treatment assessed before and after pictures of the patients. Quality of life measures consisted of embarrassment, dress, social, and work components, measured on a 5-point scale. Following the 6 months of treatment, the percentages of patients achieving 50% or more repigmentation were 43%, 47%, and 51% for the Yiqiqubai alone, laser alone, and combined Yiqiqubai and laser groups, respectively (p<0.05). While the quality of life improved in all 3 treatment arms, patients in the combined treatment arm reported significantly larger improvements than the arms receiving laser or Yiqiqubai alone.

**Retrospective Studies**

In 2017, Fa et al published a retrospective analysis of 979 Chinese patients (3478 lesions) treated with the 308-nm targeted laser for vitiligo.<sup>7</sup> Patients had Fitzpatrick skin phototype III or IV and were followed for 2 years after last treatment. Repigmentation was assessed by 2 dermatologists. A total of 1374 (39%) lesions reached at least 51% repigmentation, with 1167 of the lesions reaching over 75% repigmentation. Complete repigmentation was seen in 219 lesions. Among the cured lesions, the recurrence rate was 44%. Patients with longer disease duration and older age experienced significantly lower efficacy rates. Application of 16 to 20 treatments resulted in higher repigmentation rates than fewer treatments, and increasing the number of treatments beyond 21 did not appear to improve repigmentation rates. There was no discussion of adverse events.

In another 2017 retrospective analysis, Dong et al evaluated the use of a medium-band (304-312 nm) targeted laser for treating pediatric patients (age ≤16 years) with vitiligo.<sup>8</sup> Twenty-seven patients (95 lesions) were evaluated by 2 dermatologists following a mean of 20 treatments

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(range, 10-50 treatments). After 10 treatment sessions, 37% of the lesions reached 50% or more repigmentation. After 20 treatment sessions, 54% of the lesions achieved 50% or more repigmentation. Six children experienced adverse events such as asymptomatic erythema, pruritus, and xerosis, all resolving in a few days.

**Section Summary: Targeted Phototherapy**

A number of RCTs and retrospective analyses have evaluated targeted phototherapy for treating vitiligo. The studies have tended to have small sample sizes, and few were designed to isolate the effect of laser therapy. Moreover, studies were heterogeneous (eg, duration and frequency of therapy sessions, different interventions or combinations of interventions, different comparison interventions). These characteristics made it difficult to pool study findings or to draw conclusions about the efficacy of targeted phototherapy for vitiligo. Two meta-analyses were attempted; however, one could not be verified because the selected studies were not available in English, and one estimate was imprecise due to the small number of studies and participants. Also, studies have suggested a potential for blistering and slight erythema with targeted phototherapy. Larger studies with representative patient populations and standard of care comparators (eg, NB-UVB) are needed to evaluate efficacy and adverse outcomes.

**PSORALENS WITH ULTRAVIOLET A**

**Systematic Reviews**

In 2017, Bae et al published a systematic review and meta-analysis on the use of phototherapy for the treatment of vitiligo.<sup>9</sup> The literature search, conducted through January 2016, identified 35 unique studies for inclusion with 1201 patients receiving NB-UVB and 227 patients receiving PUVA. Category of evidence and strength of recommendation were based on study design of the selected studies. The outcome of interest was repigmentation rate. Meta-analytic results are summarized in Table 1. Adverse events were not discussed.

**Table 1. Response Rates for NB-UVB and PUVA in the Treatment of Vitiligo by Treatment Duration**

Treatment	Duration, mo	≥50% Repigmentation (95% CI), %	≥75% Repigmentation (95% CI), %
NV-UVB	6	37.4 (27.1 to 47.8)	19.2 (11.4 to 27.0)
NV-UVB	12	56.8 (40.9 to 72.6)	35.7 (21.5 to 49.9)
PUVA	6	23.5 (9.5 to 37.4)	8.5 (0 to 18.3)
PUVA	12	34.3 (23.4 to 45.2)	13.6 (4.2 to 22.9)

Adapted from Bae et al (2017).<sup>9</sup>

CI: confidence interval; NV-UVB: narrowband ultraviolet B; PUVA: psoralens with ultraviolet A.

The 2015 Cochrane review of trials on treatments for vitiligo (discussed in the previous section), identified 12 RCTs evaluating PUVA.<sup>1</sup> Four trials assessed oral PUVA alone and eight assessed PUVA in combination with other treatments (eg, calcipotriol, azathioprine, polypodium leucotomos, khellin, or surgical treatment). Seven of the 8 studies used 9-methoxypsoralen. A meta-analysis of 3 studies that compared PUVA with NB-UVB found that a larger proportion of patients receiving NB-UVB achieved >75% repigmentation compared with patients receiving PUVA; however, the difference was not statistically significant (RR=1.60; 95% CI, 0.74 to 3.45). Patients treated with NB-UVB experienced significantly less nausea (RR=0.13, 95% CI,



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0.02 to 0.69) and erythema (RR=0.73, 95% CI, 0.55 to 0.98) compared with patients receiving PUVA.

A 1998 meta-analysis of nonsurgical treatments for vitiligo was published by Njoo et al.<sup>10</sup> Pooled analysis of 2 RCTs evaluating oral unsubstituted psoralen plus sunlight for generalized vitiligo (97 patients) found a statistically significant treatment benefit for active treatment compared with placebo (pooled odds ratio, 19.9; 95% CI, 2.4 to 166.3). Pooled analysis of 3 RCTs, 2 of oral methoxsalen plus sun and 1 of oral trioxsalen plus sunlight (181 patients), also found a significant benefit for active treatment vs placebo for generalized vitiligo (odds ratio, 3.8; 95% CI, 1.3 to 11.3). Adverse events included nausea, headache, dizziness, and cutaneous pruritus. All studies were published before 1985, had relatively small sample sizes (CIs were wide), and used sun exposure rather than artificial UVA.

### Randomized Controlled Trial

In 2007, Yones et al published an RCT that used a psoralen formulation available in the United States.<sup>11</sup> This trial was included in both the Bae (2017) and Cochrane (2015) systematic reviews. The trial enrolled 56 patients in the United Kingdom who had nonsegmental vitiligo. Outcome assessment was blinded. Patients were randomized to twice-weekly treatments with methoxsalen hard gelatin capsules (8-MOP) PUVA (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/cm<sup>2</sup>, followed by 0.25 J/cm<sup>2</sup>-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 50% or more improvement in body surface area affected compared with 9 (36%) of 25 patients in the PUVA group. Also, 8 (32%) of 25 in the NB-UVB group and 5 (20%) of 25 of patients in the PUVA group had 75% or more improvement in the body surface area affected. Although authors did not provide p values in their outcomes 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, the 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 evidence from randomized studies, published mainly before 1985, that PUVA is more effective than placebo for treating vitiligo. Meta-analyses have shown that patients receiving NB-UVB experienced higher rates of repigmentation than patients receiving PUVA, though the differences were not statistically significant. Patients treated with PUVA experienced higher rates of adverse events such as nausea and erythema. Analyses of treatment duration found that repigmentation rates following 12 months of treatment were higher compared with rates following 6 months of treatment.



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**SUMMARY OF EVIDENCE**

For individuals who have vitiligo who receive targeted phototherapy, the evidence includes systematic reviews of randomized controlled trials. 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. Two meta-analyses were attempted; however, results from a meta-analysis could not be verified because the selected studies were not available in English, and one estimate was imprecise due to the small number of studies and participants. 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.

For individuals who have vitiligo who have not responded to conservative therapy who receive PUVA (photochemotherapy), the evidence includes systematic reviews and randomized control trials. 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. When compared with narrowband ultraviolet B in meta-analyses, results have shown that patients receiving narrowband ultraviolet B experienced higher rates of repigmentation than patients receiving PUVA, though the differences were not statistically significant. 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 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, guidelines on the diagnosis and management of vitiligo were published by a collaboration of several U.K. organizations, including the British Association of Dermatologists, the Royal College of Physicians of London, and the Cochrane Skin Group.<sup>12</sup> The guidelines included the following statements (see Table 2).

**Table 2. British Guidelines on the Diagnosis and Management of Vitiligo**

Recommendation	GOE	LOE
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.	D	4
If phototherapy is to be used for treating nonsegmental vitiligo, NB-UVB should usually be used in preference to oral PUVA.	A	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.	D	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.	D	3

GOE: grade of evidence; LOE: level of evidence; NB-UVB: narrowband ultraviolet B; PUVA: psoralens with ultraviolet A.

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**European Dermatology Forum**

In 2013, the European Dermatology Forum published consensus guidelines on the management of vitiligo.<sup>13</sup> The guidelines stated that oral psoralens with ultraviolet A are commonly used in adults with generalized vitiligo as a second-line treatment. The guidelines 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, not a systematic review of the literature.

**Vitiligo Working Group**

The Vitiligo Working Group is supported by the National Institute of Arthritis and Musculoskeletal and Skin Diseases, part of the National Institutes of Health. In 2017, the group published guidelines on current and emerging treatments for vitiligo.<sup>14</sup> The Working Group indicated that psoralens with ultraviolet A has largely been replaced by narrowband ultraviolet B, but that “PUVA may be considered in patients with darker Fitzpatrick skin phototypes or those with treatment-resistant vitiligo (level I evidence).” The Working Group also stated that “Targeted phototherapy (excimer lasers and excimer lamps) can be considered when <10% of body surface area is affected (level II evidence).”

**U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATION**

Not applicable.

**MEDICARE NATIONAL COVERAGE**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

**ONGOING AND UNPUBLISHED CLINICAL TRIALS**

A search of [ClinicalTrials.gov](http://ClinicalTrials.gov) in October 2017 did not identify any Table 2 summarizes ongoing or unpublished trials that may influence this review.

**V. DEFINITIONS**

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**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.

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**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**

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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

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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 BlueCross for benefit information.

### VII. DISCLAIMER

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*Capital BlueCross’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 BlueCross considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.*

### VIII. CODING INFORMATION

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**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:

CPT Codes®							
96900	96910	96912	96913	96920	96921	96922	

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HCPCS Code	Description
E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 sq ft or less
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 ft panel
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 ft panel
E0694	Ultraviolet multidirectional light therapy system in 6 ft cabinet, includes bulbs/lamps, timer, and eye protection
S9098	Home visit, phototherapy services (e.g., Bili-lite), including equipment rental, nursing services, blood draw, supplies, and other services, per diem

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<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
C84.00	Mycosis fungoides, unspecified site
C84.01	Mycosis fungoides, lymph nodes of head, face, and neck
C84.02	Mycosis fungoides, intrathoracic lymph nodes
C84.03	Mycosis fungoides, intra-abdominal lymph nodes
C84.04	Mycosis fungoides, lymph nodes of axilla and upper limb
C84.05	Mycosis fungoides, lymph nodes of inguinal region and lower limb
C84.06	Mycosis fungoides, intrapelvic lymph nodes
C84.07	Mycosis fungoides, spleen
C84.08	Mycosis fungoides, lymph nodes of multiple sites
C84.09	Mycosis fungoides, extranodal and solid organ sites
C84.A0	Cutaneous T-cell lymphoma, unspecified, unspecified site
L20.0	Besnier's prurigo
L20.81	Atopic neurodermatitis
L20.82	Flexural eczema
L20.84	Intrinsic (allergic) eczema
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis, unspecified
L29.8	Other pruritus
L30.1	Dyshidrosis [pompholyx]
L40.0	Psoriasis vulgaris
L40.1	Generalized pustular psoriasis
L40.2	Acrodermatitis continua
L40.3	Pustulosis palmaris et plantaris
L40.4	Guttate psoriasis
L40.8	Other psoriasis
L40.9	Psoriasis, unspecified
L41.0	Pityriasis lichenoides et varioliformis acuta
L41.1	Pityriasis lichenoides chronica
L41.3	Small plaque parapsoriasis
L41.4	Large plaque parapsoriasis
L41.5	Retiform parapsoriasis
L41.8	Other parapsoriasis
L41.9	Parapsoriasis, unspecified
L42	Pityriasis rosea
L43.0	Hypertrophic lichen planus
L43.1	Bullous lichen planus
L43.2	Lichenoid drug reaction

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<b>ICD-10-CM Diagnosis Codes</b>	<b>Description</b>
L43.3	Subacute (active) lichen planus
L43.8	Other lichen planus
L43.9	Lichen planus, unspecified
L56.3	Solar urticaria
L56.4	Polymorphous light eruption
L66.1	Lichen planopilaris
L80	Vitiligo
L90.0	Lichen sclerosus et atrophicus
L94.0	Localized scleroderma [morphea]

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**MEDICAL POLICY**

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<b>POLICY NUMBER</b>	<b>MP-2.046</b>

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**X. POLICY HISTORY**

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<b>MP 2.046</b>	<b>CAC 2/24/04</b>
	<b>CAC 11/30/04</b>
	<b>CAC 6/28/05</b>
	<b>CAC 6/27/06</b>
	<b>CAC 6/26/07</b>
	<b>CAC 5/27/08</b>
	<b>CAC 7/28/09</b>
	<b>CAC 7/27/10</b> Added medical necessity indication for pityriasis rosea.
	<b>CAC 7/26/11</b> Consensus review
	<b>10/12/11</b> FEP variation updated with FEP policy MP-2.01.07 Psoralens with Ultraviolet A (PUVA).
	<b>CAC 8/28/12</b> Deleted statement related to coverage limitation for home phototherapy units. Added new investigational statement indicating targeted



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	phototherapy is considered <b>investigational</b> for the treatment of vitiligo. Now silent on specific FDA information regarding Oxsoralen.
	<b>CAC 7/30/13</b> Consensus. No change to policy statements. References updated. Administrative code review complete.
	<b>CAC 3/25/14</b> Consensus. No change to policy statements. Rationale section added. References updated.
	<b>CAC 3/24/15</b> Consensus review. No changes to the policy statements. Background, rationale, and references updated. FEP variation updated to refer to FEP medical policy manual for light therapy for vitiligo. Coding reviewed.
	<b>CAC 3/29/16</b> Consensus review. No changes to the policy statements. References and rationale updated. Coding reviewed.
	<b>10/19/16</b> Admin update, added missing heading only. No policy changes.
	<b>Admin update 1/1/17:</b> Product variation section updated.
	<b>CAC 1/31/17</b> Minor review. Added indications for Excimer laser and lamp. Morphea added as an indication for UVB therapy. Coding reviewed added diagnoses for Morphea.
	<b>1/1/18 Admin Update:</b> Medicare variations removed from Commercial Policies.
	<b>1/5/18</b> Consensus review. No change to policy statements. Background, rationale and references updated.
	<b>8/1/18</b> Coding update.

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