



Medical Coverage Policy

Effective Date..... 9/15/2021
Next Review Date..... 9/15/2022
Coverage Policy Number 0031

Phototherapy, Photochemotherapy, and Excimer Laser Therapy for Dermatologic Conditions

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INSTRUCTIONS FOR USE

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Overview

This Coverage Policy addresses office-based phototherapy, photochemotherapy, and excimer laser therapy for dermatologic conditions. Phototherapy includes exposure to type A ultraviolet (UVA) radiation or type B ultraviolet (UVB) radiation. Photochemotherapy is exposure to UVA radiation following administration of a psoralen (e.g., methoxsalen, trioxsalen) (PUVA). Excimer laser therapy releases a spectrum of UVB wavelengths and is used to treat small, focused areas of the body. Home phototherapy may be indicated for a select subset of dermatologic conditions.

Coverage Policy

Coverage for home phototherapy devices varies across plans. Please refer to the customer's benefit plan document for coverage details.

Office-Based Phototherapy and Photochemotherapy

Office-based phototherapy and photochemotherapy* are considered medically necessary when there is failure, intolerance or contraindication to conventional medical management (e.g., topical ointments or creams, immunosuppressants) for ANY of the following dermatologic conditions:

- atopic dermatitis (i.e., atopic eczema)
- localized scleroderma
- cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides)
- lichen planus
- photodermatoses (e.g., polymorphic light eruption, actinic prurigo, chronic actinic dermatitis)
- psoriasis

Vitiligo

An initial regimen (i.e., for up to 12 weeks) of office-based phototherapy or photochemotherapy* is considered medically necessary for the treatment of localized or generalized vitiligo when EITHER of the following criteria is met:

- **vitiligo body surface area (BSA) involvement \leq 10% with BOTH of the following:**
 - failure, intolerance or contraindication to an eight consecutive week trial of at least ONE topical corticosteroid
 - failure, intolerance or contraindication to a twelve consecutive week trial of at least ONE topical calcineurin inhibitor (e.g., tacrolimus 0.03% or 0.1% ointment, pimecrolimus 1% cream)
- **vitiligo BSA involvement $>$ 10%**

Continued office-based phototherapy or photochemotherapy beyond the initial 12 weeks and for up to 52 weeks is considered medically necessary for the treatment of localized or generalized vitiligo when there is a beneficial clinical response to the previous course of treatment.

Continued office-based phototherapy or photochemotherapy beyond 52 weeks for up to and including 200 total treatments is considered medically necessary when there is a continued beneficial clinical response.

More than 200 treatment sessions of office-based phototherapy or photochemotherapy for vitiligo is considered not medically necessary.

***Office-based phototherapy includes type A ultraviolet (UVA) radiation and type B ultraviolet (UVB) radiation. Photochemotherapy includes psoralens (P) and type A ultraviolet (UVA) radiation, known as PUVA photochemotherapy.**

Other Conditions

Phototherapy or photochemotherapy is considered experimental, investigational, or unproven in any setting for any other indication, including EACH of the following dermatologic conditions:

- cicatricial alopecias
- cutaneous herpes virus
- chronic ordinary urticaria
- chronic palmoplantar pustulosis
- chronic vesicular dyshidrotic eczema
- diabetic foot ulcer
- dyshidrotic eczema
- erythropoietic porphyria
- granuloma annulare
- herpesviridae
- onychomycosis
- palmoplantar eczema, acute
- psoriatic nail disease

- pityriasis rosea
- prurigo nodularis
- uremic pruritis
- urticaria pigmentosa (cutaneous mastocytosis)

Phototherapy or photochemotherapy is considered cosmetic and not medically necessary for the treatment of alopecia areata in any setting. Please refer to the customer's benefit plan document for coverage details on cosmetic services.

Office-Based Excimer Laser Therapy

Office-based targeted excimer laser therapy (i.e., 308 nanometers [nm]) is considered medically necessary for the treatment of localized, plaque psoriasis refractory to conservative treatment with topical agents and/or phototherapy.

Vitiligo

An initial regimen (i.e., for up to 12 weeks) of office-based targeted excimer laser therapy (i.e., 308 nanometers [nm]) is considered medically necessary for the treatment of localized vitiligo when BOTH of the following criteria are met:

- failure, intolerance or contraindication to an eight consecutive week trial of at least ONE topical corticosteroid
- failure, intolerance or contraindication to a twelve consecutive week trial of at least ONE topical calcineurin inhibitor (e.g., tacrolimus 0.03% or 0.1% ointment, pimecrolimus 1% cream)

Continued office-based targeted excimer laser therapy (i.e., 308 nanometers [nm]) beyond the initial 12 weeks and for up to 52 weeks is considered medically necessary for the treatment of localized vitiligo when there is a beneficial clinical response to treatment

Continued office-based targeted excimer laser therapy (i.e., 308 nanometers [nm]) beyond 52 weeks up to and including 200 total treatments is considered medically necessary when there is a continued beneficial clinical response.

More than 200 treatment sessions of office-based targeted excimer laser therapy (i.e., 308 nanometers [nm]) for the treatment of vitiligo is considered not medically necessary.

Other Conditions

Targeted excimer laser therapy (i.e., 308 nanometers [nm]) is considered experimental, investigational or unproven in any setting for any other indication, including EACH of the following dermatologic conditions:

- atopic dermatitis (i.e., atopic eczema)
- cicatricial alopecias
- cutaneous herpes virus
- chronic ordinary urticaria
- chronic palmoplantar pustulosis
- diabetic foot ulcer
- dyshidrotic eczema
- erythropoietic porphyria
- granuloma annulare
- lichen planus
- onychomycosis
- palmoplantar eczema, acute
- pityriasis rosea
- prurigo nodularis

- psoriatic nail disease
- urticaria pigmentosa (cutaneous mastocytosis)

Excimer laser therapy is considered cosmetic and not medically necessary for the treatment of alopecia areata in any setting. Services that are cosmetic are not covered under most benefit plans.

Home Phototherapy Devices

If coverage for home phototherapy devices is available, the following conditions of coverage apply:

An appropriately sized (e.g. hand wand for hand, two-foot panel for lower leg) ultraviolet B (UVB) home phototherapy device is considered medically necessary when the above criteria for office-based phototherapy and photochemotherapy are met with ALL of the following:**

- outpatient UVB phototherapy has been utilized, demonstrated to be beneficial and is expected to be long-term
- a prescription is needed for the device, and the device and treatment regimen are prescribed by a physician
- individual is motivated and compliant to prescribed usage

****Ultraviolet cabinets are generally not covered**

Ultraviolet A (UVA) phototherapy in the home setting is considered not medically necessary.

The use of a tanning bed/unit for any reason in any setting is not considered medical in nature and as such does not meet the standard plan definition of Durable Medical Equipment. In addition, many benefit plans do not cover the use of a tanning bed/unit in any setting, including the home, for the treatment of dermatologic conditions because it is considered not medically necessary.

General Background

Dermatologic conditions are a common human illness. For example, according to the American Academy of Dermatology Association (AAD) (2021), atopic dermatitis affects up to 25% of children and 2-3% of adults and one in ten people will develop atopic dermatitis during their lifetime. Psoriasis affects approximately 7.5 million people in the United States. The AAD further states that in 2013 costs associated with treatment and lost productivity for those seeking treatment for atopic dermatitis was \$442 million. Total cost for treatment of psoriasis was estimated to be between \$51.7 and \$63.2 billion. Diagnosis of dermatologic conditions is made with a detailed history of the skin condition and a skin examination. Occasionally, additional diagnostic tools are necessary to make a definitive diagnosis (e.g., laboratory tests, skin biopsy, Wood's lamp, dermatoscope). The skin examination is focused on assessing the morphology and distribution of the lesions, color, consistency, and number and arrangement of the lesions. Treatment options vary greatly depending on the diagnosis and severity of symptoms and can include: antihistamines, medicated creams and ointments, laser therapy, ultraviolet radiation, and targeted prescription medications.

According to the National Eczema Association (2021), 19.3% of African American children have atopic dermatitis (eczema) compared to 16.1% of white and 7.8% of Asian children. It is important to note that many skin conditions (e.g., erythema, eczema, urticarial wheals, purpura, dry skin) may appear different between various skin pigmentation levels. For example, atopic dermatitis may appear brown, purple, or grey in individuals with brown or black skin and pink or red in individuals with lighter or white skin.

Office-Based Phototherapy and Photochemotherapy

Phototherapy (e.g., actinotherapy) is defined as exposure to non-ionizing, ultraviolet (UV) radiation for therapeutic benefit by inducing DNA damage. The therapy involves exposure to type A ultraviolet (UVA) radiation or type B ultraviolet (UVB) radiation or various combinations of UVA and UVB. The differences in these ultraviolet light forms are the length of the waves. UVA wavelength is 320-400 nanometers [nm], broadband (bb)

UVB is 280–320 nm and narrowband (nb) UVB is 311–312 nm. UVA is further broken down into UVA1 (340–400 nm) and UVA2 (320–340 nm). The longer wavelengths emit a lower energy level. UVA bulbs, for example, are used in tanning beds for cosmetic effects because they promote tanning using lower energy with less erythema than UVB. Photochemotherapy is exposure to UVA radiation following administration of a psoralen (e.g., methoxsalen, trioxsalen) given orally, topically, or in a bath which makes the skin more susceptible to the effects of UVA (PUVA). Combination therapy includes phototherapy or photochemotherapy with topical agents, such as tar, anthralin and corticosteroids, or with systemic agents, such as retinoids and methotrexate. Phototherapy and chemotherapy are proposed for numerous indications (e.g., atopic dermatitis, localized scleroderma, psoriasis, dyshidrotic eczema, chronic ordinary urticaria). The duration and number of treatments depends on the dermatologic condition; type, number, and location of the lesions; skin type; type of therapy (e.g., UVA, UVB, PUVA); dosage; and the response to treatment. Treatment is typically administered two to three times per week until the condition clears.

Evidence in the published peer-reviewed scientific literature, including systematic reviews, randomized controlled trials and case series, as well as professional societies and organizations support the safety and effectiveness of phototherapy and photochemotherapy for the treatment of atopic dermatitis, localized scleroderma, cutaneous T-cell lymphoma, lichen planus, photodermatoses, psoriasis, and vitiligo for patients who do not tolerate or are unresponsive to conventional medical management (e.g., oral immunosuppressive agents, biologic agents, topical and oral steroids) (Buense, et al., 2012; Khandpur and Sharma, 2012; Paul, et al., 2012; Farnaghi, et al., 2011; Dayal, et al., 2010; Jain, et al., 2010; Mahajan, et al., 2010; Sivanesan, et al., 2009; Kroft, et al., 2008; Ponte, et al., 2010; Tzaneva, et al., 2010; Pavlitsky, et al., 2008; Trott, et al., 2008; Brockow, et al., 2007; Erkin, et al., 2007; Kirke, et al., 2007; Meduri, et al., 2007; Schiener, et al., 2007; Sezer, et al., 2007; Wackernagle, et al., 2007; Boztepe, et al., 2006; Brown and Reynolds, 2006; Gambichler, et al., 2006; Gokdemir, et al., 2006; Goldinger, et al., 2006; Kreuter, et al., 2006; Wise, 2006; Vongthongsri, et al., 2006; Yones, et al., 2006; Asawanonda, et al., 2005; Berneburg, et al., 2005; El-Mofty, et al., 2005; Kollner, et al., 2005; Lebwohl, et al., 2005; El-Mofty, et al., 2004; Ibbotson, et al., 2004; Tahir, et al., 2004; Saricaoglu, et al., 2003; Scheinfeld, et al., 2003; Whitaker, et al., 2003; Reichrath, et al., 2002).

U.S. Food and Drug Administration (FDA): Phototherapy and photochemotherapy light sources are approved by the FDA 510(k) process as Class II phototherapy units for a variety of skin disorders. Examples of phototherapy light sources include: VersaClear™ Skin Therapy System (TheraLight, Inc., Carlsbad, CA), the Houva Phototherapy System with PhotoSense II™ (National Biological Corporation, Inc., Beachwood, OH), and the Psoria-Shield AURORA (Psoria-Shield, Utica, NY).

Atopic Dermatitis: Atopic dermatitis, or atopic eczema, is a chronic skin condition characterized by a dry, itchy rash on the face, elbows, hands, knees, and/or feet. In addition to skin care and avoidance of substances that might irritate the skin, topical ointments and creams, and oral corticosteroid are standard treatment options. For severe cases in adults, immunosuppressants may be prescribed.

Literature Review: The evidence in the published peer-reviewed scientific literature in the form of systematic reviews and randomized controlled trials supports UVB, nbUVB, and UVA phototherapy, PUVA, and combination treatments as safe, effective, and well-tolerated therapies for atopic dermatitis. Studies reported appreciative improvement in symptoms and in some cases long-term remission (Garritsen, et al., 2014; Tzaneva, et al., 2010; Brown and Reynolds, 2006; Wise, 2006; Meduri, et al., 2007).

Professional Societies/Organizations: The American Academy of Dermatology (AAD) (2014) recommended phototherapy for the treatment of atopic dermatitis following failure of first-line therapy, including emollients, topical steroids, and topical calcineurin inhibitors. Phototherapy can also be used for treatment in chronic disease as a maintenance therapy. The light modality, dosing and scheduling is based on various factors, such as phototherapy technique, skin type, skin cancer history, and use of photosensitizing medication. Although AAD stated that home phototherapy may be considered for a subset of patients who are unable to go to an office setting, they noted that there are no studies that document the safety and efficacy of home phototherapy for AD.

Localized Sclerodema: Localized scleroderma, also known as morphea, is a rare autoimmune and auto-limiting disease of unknown etiology characterized by sclerosis of the connective tissue and microcirculatory changes leading to thickening of the skin from excess collagen production. Resolution usually takes place within months

to years however, 10% of people will develop atrophic, deforming lesions. Clinical presentation includes “erythematous or violaceous macules, with smooth surface and white-yellowish center, which progressively becomes depressed and hardened.” This is referred to as the inflammatory stage. The stage of stable disease is apparent as the macules progress into a “white-ivory color on the central atrophic area, surrounded by a sclerotic plaque”. Treatment (e.g., medicated creams and ointments, UV light therapy, steroids, immunosuppression) is not always needed and depends on the severity of disease. (Buense, et al., 2012).

Literature Review: Systematic reviews, randomized controlled trials, and case series support the efficacy of UVA and PUVA for the treatment of localized scleroderma (Albuquerque, et al., 2019; Buense, et al., 2012; Kroft, et al., 2008; Kreuter, et al., 2006; El-Mofty, et al., 2004)

Cutaneous T-cell Lymphoma (CTCL): Cutaneous T-cell lymphoma (CTCL) is a slowly evolving form of non-Hodgkin lymphoma of the T-cell. Early stages of the disease may present as distinctive lymphoid dermatoses, such as parapsoriasis, poikiloderma atrophicans vasculare, follicular mucinosis (alopecia mucinosa), and pityriasis lichenoides. Two-thirds of CTCL cases are mycosis fungoides (MF), a form of CTCL that evolves from scaly skin patches and plaques. Sezary syndrome is an aggressive form of mycosis fungoides. CTCL may initially be treated with topical chemotherapy agents. PUVA is a widely used treatment for early cutaneous T-cell lymphoma, mycosis fungoides and Sezary syndrome. UVB for MF and Sezary is typically administered 2–3 times a week with ≥ 24 hours between treatments. A response may be seen within one month of initiation of treatment. PUVA is also typically given 2–3 times a week with 48 hours between treatments. Long-term maintenance is proposed after the initial clearing. Frequency of treatments will depend on the extent of the disease and recurrence rate (Vieyra-Garcia, et al., 2018; Olsen, et al., 2016; Zandi, et al., 2010; National Cancer Institute, 2016; Olsen, et al., 2007; Gokdemir, et al., 2006; El-Mofty, et al., 2005).

Literature Review: Randomized controlled trials and case series support the safety and efficacy of phototherapy and photochemotherapy for the treatment of CTCL. The results from the clinical trials reported significant improvement to complete remission of T-cell lymphoma and mycosis fungoides (Farnaghi, et al., 2011; Ponte, et al., 2010; Gokdemir, et al., 2006; El-Mofty, et al., 2005; Scheinfeld, et al., 2003; Whitaker, et al., 2003).

Professional Societies/Organizations: The National Cancer Institute (2018) lists PUVA and UVB phototherapy as treatment options for mycosis fungoides and Sezary syndrome with early cutaneous stages achieving the best responses. Treatment options depend on the stage of the disease.

In their guidelines for the treatment of primary cutaneous lymphomas, the National Comprehensive Cancer Network® (NCCN®) (2019) lists phototherapy as treatment options for mycosis fungoides and Sezary syndrome recommending UVB and nbUVB for patch/thin plaques and PUVA for the treatment of thicker plaques. Treatment varies based on the disease stage.

In a consensus statement on the management of mycosis fungoides and sezary syndrome, the United States Cutaneous Lymphoma Consortium stated that UVB or PUVA may be considered for individuals with stage IA, IB, or IIA mycosis fungoides. They added that PUVA may be more effective for thick plaques or folliculotropic involvement than UVB because UVA has better skin penetration properties (Olsen, et al., 2016).

Lichen Planus: Lichen planus is an inflammatory disease that usually affects the skin and/or the mouth and is characterized by recurrent, itchy, inflammatory rash and/or lesions. Since there is no cure for lichen planus, treatment is aimed at relieving symptoms. Milder cases may be treated with corticosteroid creams and ointments, anti-inflammatory drugs, and antihistamines. More severe cases may require oral or injectable corticosteroids, phototherapy and photochemotherapy.

Literature Review: Although the evidence supporting the efficacy of phototherapy and photochemotherapy for lichen planus is primarily in the form of case series and retrospective reviews, these modalities are established treatment options for this condition when conventional therapies are not effective, not tolerated or are contraindicated. Partial and complete response have been reported in patients following therapy (Iraji, et al., 2011; Pavlotsky, et al., 2008; Wackernagel, et al., 2007; Saricaoglu, et al., 2003; Reichrath, et al., 2002).

Photodermatoses (e.g., Polymorphic Light Eruption, Actinic Prurigo, Chronic Actinic Dermatitis):

Photodermatoses refers to skin conditions that are aggravated by sunlight. The primary photodermatoses include polymorphic light eruption, actinic prurigo, and chronic actinic dermatitis, also known as photosensitivity dermatitis. Solar urticaria is a rare photodermatoses characterized by pruritis, erythema, pain and wheal formation. Treatment options include avoiding sun exposure, using sunscreens, and topical and/or oral steroids. Phototherapy is viewed as a mainstay of treatment for severe cases.

Literature Review: A limited number of studies in the form of randomized controlled trials and case series have reported that photodermatoses can be successfully treated with UVA, UVB, UVA/UVB, nbUVB phototherapy, and PUVA. Phototherapy and photochemotherapy are recognized treatment options for these conditions (Gambichler, et al., 2006; Ibbotson, et al., 2004).

Psoriasis: Psoriasis is a skin disease involving thickened, red areas covered with silvery scales and characterized by chronic, recurrent exacerbations and remissions. The forms of psoriasis include plaque, pustular (e.g., palmoplantar), inverse, erythrodermic and guttate. Medical management of psoriasis may include bath solutions, moisturizers, topical corticosteroid ointments and creams, vitamin D ointment, retinoid gel and coal tar (i.e., Goeckerman treatment). Phototherapy and photochemotherapy are established treatment options for patients with psoriasis who do not respond to medical treatment.

Literature Review: Systematic reviews, randomized controlled trials, and case series support the safety and efficacy of phototherapy and photochemotherapy for the treatment of psoriasis. Studies have reported favorable response to treatment using bbUVB, nbUVB, PUVA, and followed by phototherapy (e.g., balneophototherapy). Phototherapy is considered an essential treatment option for psoriasis (Chen, et al., 2013; Paul, et al., 2012; Khandpur and Sharma, 2012; Dayal, et al., 2010; Jain, et al., 2010; Mahajan, et al., 2010; Sivanesan, et al., 2009; Trott, et al., 2008; Brockow, et al., 2007; Erkin, et al., 2007; Kirke, et al., 2007; Schiener, et al., 2007; Sezer, et al., 2007; Boztepe, et al., 2006; Goldinger, et al., 2006; Yones, et al., 2006; Vongthongsri, et al., 2006; Asawanonda, et al., 2005; Kollner, et al., 2005; Lebwohl, et al., 2005; Berneburg, et al., 2005; Tahir, et al., 2004).

Professional Societies/Organizations: The American Academy of Dermatology and the National Psoriasis Foundation issued a joint guideline on the management of psoriasis in pediatric patients that recommends the use of narrowband UVB is recommended as a treatment option for moderate to severe plaque and guttate psoriasis in the pediatric population. PUVA may be beneficial but has limited supporting evidence (Menter, et al., 2020).

In their guidelines on the treatment of psoriasis, the American Academy of Dermatology (AAD) (Menter, et al., 2010) stated that UVB phototherapy is safe and effective and nbUVB phototherapy is generally preferable and has improved efficacy compared to bbUVB phototherapy. UVB phototherapy can be given in the office or at home. PUVA is also effective and may result in long remissions, but may increase the risk for squamous cell carcinoma and malignant melanoma. The duration of treatment using phototherapy or photochemotherapy varies depending on the type of psoriasis, skin type, ultraviolet dosing, and whether nbUVB (e.g., 15–20 treatments), bbUVB (e.g., 20–25 treatments), or topical or systemic PUVA is used. Improvement may be seen within 2–4 weeks and 8–40 treatments.

In an evidence-based clinical consensus document, the National Psoriasis Foundation Medical Board stated that systemic therapy and/or phototherapy (broad and narrowband phototherapy, photochemotherapy (PUVA), systemic agents, and biologics) are recommended for patients with psoriasis affecting greater than 5% BSA; for those with less than 5% BSA affected in vulnerable areas, such as the face, genitals, hands or feet; and for other forms of psoriasis, including but not limited to erythrodermic, pustular and guttate. In addition, patients with limited affected areas and inadequate response to localized therapy or impairment in physical or mental functioning should also be considered candidates for systemic and/or phototherapy treatment (Pariser, et al., 2007).

In 2019 the American Academy of Dermatology and the National Psoriasis Foundation released a joint guideline re-affirming that ultraviolet phototherapy serves as a safe and effective treatment option of psoriasis for those with failing first line topical treatment or patients wishing to avoid systemic medication (Elmets, et al., 2019).

Vitiligo: Vitiligo is a disease resulting in a loss of pigment cells (i.e., melanocytes), producing white patches. The contrast between the white patches and unaffected skin can result in disfigurement leading to stigmatization, isolation, and low self-esteem. This contrast is most prominent in those with darker skin tones. The etiology of vitiligo is widely accepted as unknown; however, could possibly be identified as an autoimmune disease. Self-management of vitiligo includes avoiding sun exposure, and using sunscreens and self-tanning dyes. In some cases, the use of interventions that repigment the skin is only temporary and may not result in long-term or permanent results. Treatment of vitiligo using phototherapy has developed into a standard of care by proving its efficacy and safety.

Literature Review: Phototherapy and photochemotherapy is supported by the scientific literature as a safe and effective treatment option for vitiligo and is an established treatment option for patients who are unresponsive to conservative therapy. Follow-up data on the long-term effectiveness of phototherapy maintaining pigmentation are limited, but relapse has been reported in up to 25–44% of patients within 12–18 months following cessation of nbUVB therapy. Some patients have reportedly relapsed within three months (Lopes, et al., 2016; Whitton, et al., 2015; Nicolaidou, et al., 2009).

Office-Based Excimer Laser Therapy

Excimer laser, also called exciplex laser, is a form of ultraviolet laser proposed for the treatment of various dermatologic conditions including, atopic dermatitis, psoriasis and vitiligo. An excimer laser releases a spectrum of 308-nm UVB wavelengths and is used to treat small, focused areas of the body (e.g., 2 X 2 centimeters). Laser therapy is proposed to increase the precision and delivery of UVB energy to targeted tissue. The increased precision results in a faster therapeutic effect and decreases the total number of treatments needed, limits the amount of UV radiation exposure, and decreases the risk of skin cancer (Feldman, 2019). The hand-held lasers are good for hard to treat areas such as elbows, knees, palms, soles of feet and scalp. This precision makes total-body treatment with laser therapy difficult. Some propose that laser therapy is effective, safe and well tolerated when limited to less than 20% of the body surface. Treatments are typically given two to three times a week on nonconsecutive days, last for 15-30 minutes, and are given for 4–36 weeks resulting in improvement of the condition. The number of treatments required depends on multiple factors including the condition being treated, the severity of the condition, skin type, and response to treatment. A minimum of 48 hours between treatments is advised. Excimer laser therapy is an established treatment option for localized, plaque psoriasis (Menter, et al., 2010; Nicolaidou, et al., 2009). Although the therapy has been proposed for other conditions, the evidence does not support its use nor is it an established standard treatment for other conditions. Phototherapy, photochemotherapy, and excimer laser therapy are contraindicated in individuals with known photosensitivity, porphyria, or systemic lupus erythematosus.

U.S. Food and Drug Administration (FDA): Excimer lasers are approved by the FDA 510(k) process. Not all excimer lasers are approved for the treatment of the same dermatological conditions. Excimer lasers include but are not limited to the following:

- FENCER Excimer Laser System (Kera Harvest/Laser Max Medical Technologies Corporation, Visalia, CA) is approved for the treatment of psoriasis, vitiligo, leukoderma, and atopic dermatitis.
- XTRAC XL Excimer Laser System (PhotoMedex, Inc. Carlsbad, CA) is approved for the treatment of psoriasis, vitiligo, leukoderma, and atopic dermatitis.
- 308 Dermatological Excimer Lamp Phototherapy system (Quantel Medical, Hasbrouck Heights, NJ), distributed by National Biological Corporation, is approved for the treatment of psoriasis and vitiligo.
- Excilite™ and Excilite-μ (Cynosure, Inc., Chelmsford, MA) monochromatic excimer light systems are approved for the treatment of “leukoderma, psoriasis, vitiligo, eczema, and seborrheic dermatitis, for skin types I to VI”.
- Levia Phototherapy System (Lerner Medical devices, Inc., Los Angeles, CA) is “intended for use in UVB phototherapy in all skin types for the treatment of psoriasis including scalp psoriasis, vitiligo, atopic dermatitis (eczema) seborrheic dermatitis and leucoderma”. The Levia has a fiber-optic brush used for areas of the skin covered with hair.
- XTRAC Momentum Excimer Laser System (Strata Skin Sciences, Inc., St. Petersburg, FL) is indicated for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma (FDA, 2020; FDA, 2008; FDA, 2007; FDA, 2005; FDA, 2004).

Psoriasis: Excimer laser therapy is supported by the scientific literature and is an established treatment option for patients with psoriasis that is unresponsive to topical agents or phototherapy (Mudigonda, et al., 2012; Nisticò, et al., 2009; He, et al., 2007; Lapidoth, et al., 2007; Amornpinyokeit and Asawanonda, 2006; Goldinger, et al., 2006; Nisticò, et al., 2006; Kollner, et al., 2005; Pahlajani, et al., 2005; Taibjee, et al., 2005; Taneja, et al., 2003; Trehan and Taylor, 2002; Rodewald, et al., 2002; Feldman, et al., 2002).

Professional Societies/Organizations: In 2019, the American Academy of Dermatology and the National Psoriasis Foundation released a joint guideline recommending targeted UVB phototherapy, including excimer, for use in adults with localized plaque psoriasis. Treatment should occur 2-3 times per week (Elmets, et al., 2019).

In a guideline on the treatment of psoriasis, the American Academy of Dermatology (AAD) recommends the use of excimer laser therapy for the treatment of mild, moderate or severe psoriasis with less than 10% body surface area involvement. Initial dosage depends on the skin type and plaque characteristics and thickness. Treatment is typically administered two to three times a week until the condition clears (average of 10–12 weeks). Mean remission time is reported to be 3.5–6 months (Menter, et al., 2010).

In an evidence-based clinical consensus document, the National Psoriasis Foundation Medical Board recommended excimer laser treatments for localized therapy for psoriasis that affects less than 5% body surface area (Pariser, et al., 2007).

Vitiligo: Evidence in the published peer-reviewed scientific literature is in the form of open, prospective studies and systematic reviews that support the safety and effectiveness of excimer laser therapy for the treatment of medically refractory vitiligo. The data suggests that there are no significant differences in outcomes between excimer lamps and excimer lasers. Pruritus, burning sensation, and dryness were noted as mild side effects that did not interrupt treatment. (Lopes, et al., 2016; Whitton, et al., 2015; Nisticò, et al., 2009).

Phototherapy, Photochemotherapy, and Excimer Laser Therapy for Other Conditions:

Phototherapy, photochemotherapy and/or excimer laser therapy have been proposed for numerous other dermatologic conditions including atopic dermatitis, cicatricial alopecias, chronic ordinary urticaria, chronic palmoplantar pustulosis, chronic vesicular dyshidrotic eczema, diabetic foot ulcers, dyshidrotic eczema or acute palmoplantar eczema (vesicular eczema, pompholyx, cheiropompholyx or pedopompholyx), erythropoietic porphyria, granuloma annulare, herpesviridae or cutaneous herpes virus (e.g., herpes simplex type 1 and 2, varicella-zoster virus, human herpesvirus 7, Kaposi sarcoma), lichen planus, onychomycosis, pityriasis rosea, psoriatic nail disease, prurigo nodularis or nodular prurigo, uremic pruritis and/or urticaria pigmentosa (cutaneous mastocytosis).

There is insufficient evidence in the published peer-reviewed literature to support phototherapy, photochemotherapy and excimer laser therapy for these other conditions, nor are these therapies an established treatment option. Studies are primarily in the form of retrospective reviews, case series with small patient populations and short-term follow-ups (e.g., five weeks to eight months) or case reports. Outcomes were conflicting and/or reported no improvement. Some studies combined phototherapy with topical steroids and have not investigated phototherapy as a monotherapy for a specific condition (Obeid, et al., 2020; Gupta, et al., 2019; Ma, et al., 2019; Qureshi, et al., 2019; Simonsen, et al., 2017; Wang, et al., 2017; Fertig and Tosti, 2016; Su, et al., 2016; Crowley et al., 2015; Manhart and Rich, 2015; Sanchez-Regana, et al., 2015; Armstrong, et al., 2014; Bristow, 2014; Dillenburg, et al., 2014; Gupta and Simpson, 2013; Ledon, et al., 2012; Kelley and Rashid, 2011; Ko, et al., 2011; Navarini, 2011; Alkhalifah, et al., 2010; Brenninkmeijer, et al., 2010; Tan, et al., 2010; Lim, et al., 2009; Nisticò, et al. 2009; Engin, et al., 2008; Chuh, et al., 2007; Sezer, et al., 2007; Baltás, et al., 2006; Chalmers, et al., 2006; Gambichler, et al., 2005; Petering, et al., 2004; Trehan and Taylor, 2004).

Alopecia Areata: Alopecia areata is an autoimmune disorder affecting hair follicles and sometimes the nails. The hair stops growing and suddenly starts falling out in patches from the roots. The patches of hair loss enlarge and then grow back. The patient can experience total scalp hair loss (alopecia totalis), loss of all hair on the body (alopecia universalis) or diffuse thinning of the hair (alopecia areata incognita). Pitting and drainage of the nails may be seen in 10% of cases. Alopecia sometimes starts after a stressful event. There is no reliable cure for the disease. Spontaneous remission occurs in up to 80% of patients. Scalp creams, corticosteroids (topical and

injectable) and contact immunotherapy have been used, but have not been shown to alter the course of the disease. (New Zealand Dermatologic Society, 2015; British Association of Dermatology, 2012)

Literature Review: Phototherapy, PUVA and excimer laser therapy have been proposed as treatment options but there is insufficient evidence in the published peer-reviewed scientific evidence to support these therapies for the treatment of alopecia areata. There is little documented evidence that UVB is effective and the limited success and long-term safety, side effects and a high relapse rate have curtailed the use of PUVA. Overall, studies investigating the effectiveness of UVB, PUVA and excimer laser are primarily in the form of case series and retrospective reviews with small patient populations (n=3–18) and short-term follow-ups (e.g., five weeks to six months). Outcomes varied depending on the type of alopecia and some patients had no response to therapy (Gupta, et al., 2019; Alkhalifah, et al., 2010;).

A meta-analysis completed by Gupta et. al. (2019) concluded that there were only four studies (n=105) testing the efficacy of 308-nm excimer laser therapy for alopecia areata. The study compared the excimer laser treatment versus a non-treatment group. The author concluded that treatment was effective vs the non-treatment group (p<0.0009). While this study does conclude that excimer laser therapy can be effective for alopecia areata, it is limited by the small patient populations, heterogeneity of outcome measures and the need for larger controlled studies.

Atopic Dermatitis (i.e., Atopic Eczema)

Literature Review: There are a limited number of studies evaluating excimer laser therapy for the treatment of atopic dermatitis. Studies are primarily in the form of case series or retrospective reviews with small patient populations and short-term follow-ups (Brenninkmeijer, et al., 2010; Baltás, et al., 2006).

Brenninkmeijer et al. (2010) conducted a within patient, randomized controlled trial (n=10) to compare the safety and efficacy of 0.05% topical clobetasol propionate (CP) ointment to excimer laser (EL) therapy for the treatment of prurigo atopic dermatitis. The patients had more than four symmetrical prurigo nodules on the lower and upper extremities that had persisted for six months or longer. Treatment was randomized to either the right or left side of the patient's body. Laser therapy was administered for ten weeks. Compared to baseline scores, both sides showed a significant improvement of mean Physician Assessment of Individual Signs (PAIS) (p<0.001) during follow up weeks 14–34. At week 34, the EL treated nodules had a significantly better PAIS score compared to the CP treated nodules (p<0.05). More patients reported marked improvement following EL (n=7) compared to CP (n=4). Less relapse of disease was seen following EL treatment. There was no significant difference in the pruritus scores between the two treatment groups. Author noted limitations of the study included the small patient population, selection of more severely affected patients, loss of blinding due to sustained hyperpigmentation in the EL group, and the use of various radiant exposures.

Professional Societies/Organizations: Due to the lack of evidence, the American Academy of Dermatology (ADD) (2014) does not recommend laser therapy as a treatment modality for atopic dermatitis.

Cicatricial Alopecia: Cicatricial (scarring) alopecia (hair loss), also called scarring alopecia or scarring hair loss, refers to a diverse group of rare disorders that destroy the hair follicles, replaces them with scar tissue, and causes permanent hair loss. Cicatricial alopecias are classified as primary or secondary. Primary cicatricial alopecias are inflammatory disorders of the scalp in which the hair follicle is the target of destruction. Primary disorders are classified as lymphocytic or neutrophilic. Lymphocytic cicatricial alopecias include lichen planopilaris, frontal fibrosing alopecia (FA), central centrifugal cicatricial alopecia (CCCA) and discoid lupus erythematosus. Neutrophilic cicatricial alopecias include folliculitis decalvans and dissecting cellulitis. Secondary cicatricial alopecia is destruction of the hair follicle from disorders that cause diffuse scarring of the dermis, including burns, radiation, severe skin infections, localized scleroderma, and scalp tumors. Symptoms of itching, burning, pain, or tenderness usually signal ongoing activity. Signs of scalp inflammation include redness, scaling, and pustules. In some cases there are very few signs and symptoms. A punch biopsy of the scalp is indicated to identify the type of inflammation, degree of activity and other changes in the scalp. Treatment depends on the type of cicatricial alopecia and includes anti-inflammatory agents (e.g., topical or intralesional steroids), calcineurin inhibitors, tetracyclines, hydroxychloroquine, and cyclosporin. Discontinuation of traumatic hair care practices is an essential aspect of treatment of CCCA. Hair restoration surgery or scalp reduction are surgical

treatment performed for cosmetic benefits and are only considered in individuals with a one to two year period of inactive disease (National Organization for Rare Disorders. [NORD], 2018; Shapiro, 2018; NORD, 2016; New Zealand Dermatology Society, 2014).

Literature Review: Studies have primarily been in the form of retrospective reviews and case series with small patient populations and short-term follow-ups. Additional high quality studies are needed to assess the safety and efficacy of phototherapy, photochemotherapy, and excimer laser therapy for the treatment of cicatricial alopecia (Fertig and Tosti, 2016; Navarini, 2011).

Chronic Vesicular Dyshidrotic Eczema: Chronic vesicular dyshidrotic eczema is a condition more commonly seen in young adults and those who have: another type of eczema, hay fever, an allergy (e.g., nickel or cobalt), sweaty hands, a family history of eczema, a personal history as a metal worker or mechanic, or have worked with cement. It is characterized by tiny, itchy, fluid filled blisters either on the hands, feet, or both. Treatment consists of soaks and cool compresses, corticosteroids, antihistamines, moisturizers or a barrier cream, pimecrolimus or tacrolimus ointment, or ultraviolet light therapy (American Academy of Dermatology Association, 2020).

Literature Review: Evidence in the peer reviewed literature is limited to comparative and non-controlled trials with short-term follow-up and small patient populations. Additional high quality randomized controlled trials are necessary to evaluate the long-term safety and efficacy of phototherapy, photochemotherapy, or excimer laser therapy for the treatment of vesicular dyshidrotic eczema (Sezer, et al., 2007; Petering, et al., 2004).

Petering et al. (2004) randomized high-dose UVA1 to PUVA for the treatment of chronic vesicular dyshidrotic eczema on the palms and backs of hands of 27 patients. Each hand was randomly treated with a different therapy. At the end of three weeks, the Dyshidrosis Area and Severity Index (DASI) scores improved to nearly half the pretreatment scores in both hands with no significant differences between the treatments.

Diabetic Foot Ulcer: Diabetic foot ulcers, characterized by full thickness wounds below the level of the ankle, are the result of peripheral insensitivity, neuropathy, and tissue damage. A lack of sensation leads to a reduction in awareness of potentially damaging foreign bodies and injuries on the part of the individual. It is that between 15–25% of individuals with diabetes will develop diabetic foot ulcers at some point in their lives. Disparities exist with prevalence ranging from 2% in high income countries to 15–25% in low and middle income countries. The presence of diabetic foot ulcers carries risk for infection, hospitalization, and amputation.

A Cochrane systematic review (Wang, et al., 2017) of randomized controlled trials evaluated phototherapy for the treatment of open foot ulcers in adult diabetics. Included studies compared 1) phototherapy with sham phototherapy, no phototherapy, or other physical therapy modalities; 2) different forms of phototherapy; or 3) phototherapy of different output power, wavelength, power density, or dose range. Eight studies (n=316) met inclusion criteria. No studies reported valid data for time to complete wound healing. Meta-analysis of four studies (n=116) indicated that more wounds treated with phototherapy experienced more healing compared with no phototherapy or placebo. Results from individual trials (n=16–84) generally suggested that after two to four weeks of treatment phototherapy may have resulted in a greater reduction in ulcer size. Analyses for quality of life (n=28) and amputations (n=23) showed no clear differences between phototherapy and no phototherapy or placebo. No significant adverse events were reported. The level of evidence was considered low due to the small patient populations, methodological flaws and unclear or high risk of bias. Large, well-designed randomized controlled trials are needed to confirm whether phototherapy is an effective treatment option for diabetic foot ulcers.

Lichen Planus: Lichen planus is an inflammatory disease that usually affects the skin and/or the mouth and is characterized by recurrent, itchy, inflammatory rash and/or lesions. Since there is no cure for lichen planus, treatment is aimed at relieving symptoms. Milder cases may be treated with corticosteroid creams and ointments, anti-inflammatory drugs, and antihistamines. More severe cases may require oral or injectable corticosteroids, phototherapy and photochemotherapy.

Literature Review: There is insufficient evidence in the published peer-reviewed literature to support the efficacy of excimer laser therapy for the treatment of lichen planus. Studies are primarily in the form of case studies with small patient populations (Trehan and Taylor, 2004; Dillenburg, et al., 2014).

In a randomized controlled trial, Dillenburg, et al. (2014) compared the application of topical clobetasol propionate gel (0.05%) three times a day (n=21) to laser irradiation (InGaAlP; MM Optics, São Carlos, São Paulo, Brazil) three times a week (n=21) for the treatment of atrophic and erosive oral lichen planus. Both groups showed initial improvement. At the 60-day follow-up the laser group had one recurrence and the clobetasol group had 10 recurrences. At the 90-day follow-up the laser group showed a significant improvement in the resolution of lesions ($p < 0.001$) and exhibited more hyperkeratotic lesions and fewer atrophic/erosive lesions than the clobetasol group ($p < 0.001$). The difference in recurrence between the groups at day 90 was not significant ($p = 0.276$). There were no reported side effects in the laser group. According to the authors, this is the first known comparison study of laser therapy vs. clobetasol. Additional studies with larger patient populations and long-term follow-up are needed to validate the results of this study.

Herpesviridae: Herpesviridae, also known as herpesviruses, is a common viral infection of the skin including but not limited to: herpes simplex viruses (i.e., HSV-1 and HSV-2), varicella zoster virus, Epstein-Barr virus, human cytomegalovirus, human herpes 6, human herpes 7, and Kaposi's sarcoma virus. Common among herpesviruses is a vesicle on an erythematous base along with a period of latency. Transmission most commonly occurs either through close physical contact or contact with infected secretions. The gold standard for treatment is the use of antivirals such as acyclovir (Whitley, 1996).

Kelley and Rashid (2011) conducted a systematic review to evaluate published studies investigating phototherapy for the treatment of Herpesviridae (n=267). Eleven clinical trials and case reports included patients with herpes simplex, varicella-zoster, human herpesvirus, and Kaposi sarcoma. Studies included case reports or case series and randomized controlled trials with small patient populations, short-term follow-ups and various types of herpes. Long-term studies with large patient populations comparing phototherapy with conventional treatment modalities are needed. Phototherapy regimens for Herpesviridae have not been established.

Onychomycosis: Onychomycosis is an infection in the nail bed and nail plate caused by any type of fungus (e.g., yeasts, nondermatophyte molds). The three main types of dermatophytic onychomycosis (also called tinea unguium) are distal subungual, proximal subungual, and white superficial. Dermatophyte fungi (e.g., *Trichophyton* sp.) are more likely to be pathogenic than nondermatophyte fungi, also referred to as molds (e.g., *Fusarium* sp.). Other types of onychomycosis include endonyx and totally dystrophic. One of several fingernails and/or toenails may be involved, but onychomycosis is more common on toenails. Onychomycosis can cause nail discoloration, thickening, irritation, pain and detachment of the nail plate. The presence of diabetes or other immunocompromised conditions may increase the risk of cellulites or other types of bacterial infection.

Treatment depends on the underlying cause and the patient's comorbidities. Oral medications (e.g., terbinafin and itraconazole) may be used in immunocompromised patients. A topical antifungal nail lacquer with or without an oral agent may be indicated. Surgery may be used to treat an isolated nail infection involving only one digit or for the treatment of a dermatophytoma (i.e., collection of dermatophytes in solid form under the nail). *Candida* onychomycosis responds to oral agents, but it is prone to relapse if the underlying reason for the infection is not resolved. Long-term recurrence rates of 20%–50% have been reported.

Because of the varied response and side effects of oral agents and the high relapse rates, additional nonsystemic treatment modalities are being investigated. Phototherapy and laser therapy have been proposed for the treatment of onychomycosis but there is insufficient evidence in published clinical trials to support the safety and efficacy of these modalities (Durme, 2012; Gupta, et al., 2012; Hoy, et al., 2012).

Ma et al. (2019) conducted a systematic review and meta-analysis on available literature to evaluate the safety and effectiveness of laser treatments for onychomycosis. Thirty-five studies met the inclusion criteria of randomized controlled trial or clinical study in which the onychomycosis group received only laser treatment; onychomycosis diagnosed by mycological exam; study purpose related to the efficacy of laser treatment for onychomycosis; patients had not been treated with systemic antifungal drugs during the preceding six months and had no other clinical manifestations associated with skin diseases; and mycological cure rate and clinical

cure rate of diseased nail reported. Studies were excluded if case report; duplicate publication; conference papers, systematic reviews, and meta-analyses; and studies in which laser treated group received other forms of treatment. The thirty five studies included five randomized controlled trials (n=1723 patients; n=4278 diseased nails). Adverse reactions were reported to be transient hemorrhage and mild to moderate burning sensations. There were no serious adverse reactions reported. The primary outcome measure recorded was mycological cure rate and safety profile. The overall mycological cure rate was 63.0% (95%CI 0.53-0.73); the mycological cure rate associated with the 1064-nm Nd: YAG laser was 63.0% (95%CI 0.51-0.74); and that of CO2 lasers was 74.0% (95%CI 0.37-0.98). While the author concluded that laser treatment of onychomycosis is safe and effective, of the thirty five studies only five are RCTs. Those RCTs are noted to have small patient populations; heterogeneity of protocol and treatment lasers; and short term follow-ups.

Bristow (2014) conducted a systematic review of the literature to evaluate the effectiveness of laser therapy for the treatment of onychomycosis. Two randomized controlled trials, four comparative studies with no control groups and four case series met inclusion criteria. Although some studies reported improvement in onychomycosis, the outcomes were conflicting and the study methodology was heterogeneous and of poor quality. Some studies reported recurrence suggesting that laser therapy only had a temporary effect. Additional limitations of the studies included small patient populations (n=8–131) with predominantly short-term follow-ups of < 24 weeks. Several of the studies excluded patients with severe or dystrophic disease. The authors noted that there is no consensus on laser effectiveness.

Gupta and Simpson, 2013 conducted a systematic review to determine the efficacy of laser therapy for the treatment of onychomycosis. A review of the literature identified three basic science articles, five peer-reviewed articles, and four pending clinical trials. The authors concluded that studies with large patient populations, mycologic examination before and after treatment, long-term follow-ups and standardized outcome measures are needed to determine if laser therapy is effective for the treatment of onychomycosis or comparable to traditional pharmacotherapeutics.

Ledon et al. (2012) conducted a systematic review of published peer-reviewed studies for laser and light therapy for the treatment of onychomycosis. Ten clinical trials, primarily case series, met inclusion criteria. No studies included UV light or excimer laser therapy for the treatment of this condition.

Psoriatic Nail Disease: Psoriatic nail disease, psoriatic nail dystrophy or nail psoriasis occurs in up to 55% of individuals with skin psoriasis, but nail psoriasis can occur without the presence of skin psoriasis. Nail psoriasis may involve pitting, discoloration (white or yellow-red), onycholysis (separation of the nail plate from the nail bed), scaling under the nail (subungual hyperkeratosis), crumbling, thickening and horizontal lines in the nail. Psoriasis can affect fingernails and toenails. Nail psoriasis can lead to pain, tenderness, functional disability and secondary bacterial or fungal infections. Scrapings and/or biopsy may be necessary to confirm the diagnosis.

Topical therapies such as corticosteroids, calcipotriol, tazarotene, and tacrolimus creams and ointments may be helpful in mild or early nail psoriasis. For individuals who also have severe skin psoriasis and/or psoriatic arthritis, a systemic or biologic treatment can reduce symptoms overall. Nail improvement may lag behind clearing of psoriasis plaques on the body by several months. It can take six months to a year for an affected nail to grow out and be replaced by a new nail (New Zealand Dermatology Society, 2016; Manhart and Rich, 2015; Crowley, et al., 2015; Schons et al., 2014).

Literature Review: There is insufficient evidence in the published peer-reviewed literature to support the safety and efficacy of phototherapy, photochemotherapy, or excimer laser therapy for the treatment of psoriatic nail disease. Studies are primarily in the form of small retrospective reviews with short term follow-up (Crowley et al., 2015; Manhart and Rich, 2015; Sanchez-Regana, et al., 2015; Armstrong, et al., 2014).

Professional Societies/Organizations: Based on a systematic review, a 2015 consensus statement for the treatment of nail psoriasis from the Medical Board of the National Psoriasis Foundation does not recommend phototherapy, PUVA or excimer laser therapy for the treatment of nail psoriasis (Crowley, et al., 2015).

Uremic Pruritis: Also known as chronic kidney disease-associated pruritus, uremic pruritis is frequently seen with end-stage renal disease. The cause is uncertain however, parathormone, histamine, calcium, and

magnesium are suspected to be causative factors. Treatment options consist of topical treatment with or without anti-inflammatory compounds, systemic treatment with gabapentin or other drugs, phototherapy, or acupuncture (Mettang and Kremer, 2015).

Simonsen et al. (2017) conducted a systematic review of the literature to assess treatment options for uremic pruritus. A total of 44 randomized controlled trials evaluating 39 different treatments were included in the review. Regarding phototherapy, four studies (n=112) met inclusion criteria. Three studies compared UV-B to UV-A therapy and one study evaluated narrow-band UVB. Dosages varied based on the patient's skin characteristics. The two studies using broadband UV-B indicated a significant benefit in favor of UV-B therapy over UV-A. However, the study comparing narrow-band UV-B to UV-A showed no statistically significant benefit of narrow-band UV-B therapy compared to UV-A therapy. Sunburn and tanning were noted side effects of the UV-B therapy. Additional studies are needed to support the effectiveness of phototherapy for the treatment of uremic pruritus.

Ko et al. (2011) conducted a randomized controlled trial to evaluate the efficacy of nbUVB (n=11) compared to a control group (n=10) who received no treatment for uremic pruritis in patients with stage III–V chronic kidney disease. At the 12-week follow-up, both groups showed significant improvement in the visual analogue scores (VAS) but there were no significant differences between the groups. Based on an interview questionnaire, the nbUVB groups reported improvement in the percentage of affected skin (p=0.004), in difficulty falling to sleep (p=0.02) and sleep disturbance (p=0.01). Phototherapy did not have a significant effect in reducing pruritis intensity compared to the control group.

Home Phototherapy

In some cases, UVB phototherapy may be transitioned to home use under the supervision of a physician if the individual has extensive, widespread disease (e.g., psoriasis) that is going to require long-term use and office-based phototherapy has been proven to be effective. Home devices emitting predominantly narrowband UVB phototherapy are used primarily for the treatment of psoriasis and require that the patient be motivated, reliable, adherent to instructions, able to administer the treatment correctly, keep records of exposure, and attend regular follow-up visits. Opponents to home therapy cite issues related to poor patient compliance, suboptimal efficacy, and greater potential for phototoxicity, erythema, burns, carcinogenesis and photoaging. Some propose limiting home phototherapy to those with overwhelming difficulties in traveling to a facility. Home devices are available in a variety of sizes to accommodate whole body treatment, hand/foot treatment, or localized treatment. Once the size of unit is determined, a decision will be made by the physician as to the type of UVB light source indicated for treatment. The physician may prescribe bbUVB or nbUVB. The number of bulbs needed will be determined based on the size of the unit. (Lapolla, et al., 2011; Menter, et al., 2010; Rajpara, et al., 2010).

UVA phototherapy is primarily used in combination with psoralen (i.e., PUVA) for the treatment of disease (e.g., psoriasis) and is administered in an outpatient setting. On its own, UVA is ineffective in treating conditions such as psoriasis and atopic dermatitis and is therefore not generally used in the home setting.

Tanning beds, or units, which typically emit UVA, are used for self-tanning solely for the purpose of improvement in appearance (i.e., cosmetic); they are not medical devices designed to be used to administer physician-prescribed treatment for a dermatologic condition.

U.S. Food and Drug Administration (FDA): The Panosol II® line of devices (National Biological Corporation, Inc., Twinsburg, OH) first received FDA approval through the 510(k) process December 24th, 1990 and is indicated for numerous dermatological conditions. This series of devices is available in either two or six foot stand-alone panels and is capable of providing narrowband UVB and/or UVA therapy.

Hand and foot UVB units may be in the form of a combined unit or may be individual units. A combined unit has the appearance of a desk and allows the patient to place their hands and feet into the unit, receiving treatment simultaneously. One such example is the Hand/Foot II™ device (National Biological Corporation, Inc., Twinsburg, OH) that originally received FDA approval through the 510(k) process on July 24, 1987. This device is designed for localized treatment of the hands or feet and is capable of providing narrowband UVB, broadband UVB, or UVA therapy. On March 20th, 2017, the FDA issued a class two recall for this device noting that the device may be able to be turned on with the key switch rather than the timer. As such, individual patients were contacted and

replacement devices were distributed. Defective devices were returned. Individual hand and foot units may have the appearance of a tabletop device such as the SolRX™ 500 Series (Solarc Systems, Inc., Ontario, Canada) which originally received FDA approval through the 510(k) process on September 10, 2003. The device used the National Biological Hand/Foot device as its predicate and is indicated, with a prescription, as spot treatment of psoriasis, vitiligo, and atopic dermatitis.

Hand held devices are available as well including the DermaPal with Digital Timer device (Daavlin Distributing Co., Bryan, OH) that received FDA approval through the 510(k) process on January 1st, 2008. This device is intended for use under the direction of a physician with a prescription for the treatment of psoriasis, vitiligo, and atopic dermatitis. The Levia Phototherapy System (Lerner Medical Devices, Inc., Grand Rapids, MI) that received FDA approval through the 510(k) process on February 13th, 2004. This device is indicated to provide UVB therapy for the treatment of scalp psoriasis, vitiligo, atopic dermatitis, seborrheic dermatitis, and leukoderma. Another example of a hand held device is the Skylit Phototherapy System (Skylit Medical, La Jolla, CA) that was given FDA approval through the 510(k) process on May 23rd, 2017. This device is indicated for the treatment of psoriasis, vitiligo, atopic dermatitis, seborrheic dermatitis, and leukoderma. It differs from the other examples given in that it works with an app that serves as the main interface to operate the device. A prescription is submitted by the ordering provider with all treatment parameters entered into the app. The user can then set treatment times while the app delivers the correct dosage and time limit for treatment. This device also integrates the assistance of a “careprovider” who’s function it is to educate, encourage compliance, monitor for non-responsiveness, and communicate with the prescribing physician. The device is also known under the trade names “Clarify” and “Zerigo”.

Literature Review: A Hayes Technology Brief (2013; reviewed 2015) stated that although the overall body of evidence is low, the data suggested that home UVB for the treatment of moderate to severe psoriasis is effective and well tolerated. Patient adherence was generally high and there were no identified safety issues. The Brief included one multicenter randomized controlled study, one 2-phase prospective comparative study, and three prospective case series.

In a single-blind randomized controlled trial, Koek et al. 2009 compared the outcomes of outpatient UVB therapy (n=98) to home UVB therapy (n=98) for patients treated for mild to severe psoriasis. After the completion of therapy, the first 105 consecutive patients were followed for one year. Outcomes were measured by the self-administered psoriasis area and severity index (SAPASI) and the psoriasis area and severity index (PASI). Treatment effect indicated by the mean decline in the PASI and SAPASI scores was significant ($p < 0.001$) and similar across groups ($p > 0.3$) indicating that home therapy was as good as and in some cases, superior (SAPASI 90) to outpatient therapy. Improvement in quality life for home patients was rated as a 42% compared to 23% for outpatients. Total cumulative doses of ultraviolet B light and the occurrence of short term side effects were not significantly different between the groups.

Use Outside of the US

The European Dermatology Forum in conjunction with the European Academy of Dermatology and Venereology published guidelines on the management of lichen planus states that broad and narrowband UVB are suggested for the treatment of cutaneous lichen planus while photochemotherapy and excimer laser can be considered. The guideline also states that photochemotherapy and narrow and broadband UVB can be considered in the treatment of mucosal lichen planus (Ioannides, et al., 2020).

In 2012, an initiative was formed in Europe called “Single Hub and Access point for pediatric Rheumatology in Europe” (SHARE) in an effort to disseminate diagnosis and management best practices for children and young adults with rheumatic disease including juvenile localized scleroderma. Based on randomized controlled trials, SHARE fully recommended the use of medium dose UVA as a means to improve skin softness in isolated morphea lesions stating that while the data is limited, it appears to have a good safety profile and efficacy in children (Zulian, et al., 2019).

In a consensus-based European guideline for the treatment of atopic eczema in adults and children, the European Academy of Dermatology and Venereology (EADV) recommended the use of medium dose UVA and narrow band UVB for the treatment of atopic dermatitis in adults. The EADV also stated that narrowband UVB is recommended over broadband UVB since it has a better safety and efficacy profile (Wollenberg, et al., 2018)

The British Association of Dermatologists (BAD) and UK Cutaneous Lymphoma Group (UKCLG) 2018 guidelines for the management of primary cutaneous lymphomas stated the following regarding phototherapy and the treatment of stage IA-IIA mycosis fungoides (MF):

- Phototherapy is the “standard of care” for the treatment of early stages of MF but the duration of response may be limited. The risk of skin cancer limits the number of treatments that can be given in a lifetime.
- Narrowband ultraviolet UVB (311–313 nm) and broadband UVB (290– 320 nm) can produce high complete response rates. Response rates are more likely in patients with only patches.
- High-dose UVA1 phototherapy (340–400 nm), which penetrates more deeply than both UVB and UVA, has shown clinical efficacy in small case series.
- High complete response rates for PUVA in early stages have been reported.
- The precise therapeutic role of excimer laser has not been established.

Additional statements included:

- PUVA can often be used as salvage therapy for stage IVA2-B MF and Sezary syndrome (SS).
- Overall complete response rates for treatment combining PUVA and interferon alpha appear to be similar to those with PUVA alone.
- Results achieved by combining PUVA with retinoids (acitretin) are similar to results with PUVA alone.
- Although there is a lack of data, combination regimens involving PUVA have been utilized as first-line treatment for patients with erythrodermic MF. Patients with SS tolerate PUVA poorly.
- Combination PUVA regimens are rarely indicated as first-line therapy for tumor or nodal disease, but may be used as an adjuvant or salvage therapy for patients with persistent cutaneous disease following debulking treatment for cutaneous tumors or nodal/visceral disease. However there is a lack of evidence supporting this use.

The European Dermatology Forum stated in a guideline on the diagnosis and treatment of sclerosing skin diseases, that phototherapy should be a first-line treatment for mild skin fibrosis and that a medium dose UVA should be the first choice of treatment among the various phototherapies (Knobler, et al., 2017).

The British Association of Dermatologists' and British Photodermatology Group joint guidelines (2016) for the safe and effective use of PUVA included the following recommendations based on case controls or cohort studies:

- PUVA should usually be offered before oral systemic therapy for patients with chronic plaque psoriasis that has not responded adequately to other therapies, including narrowband UVB
- Although PUVA may occasionally be appropriate as a first-line phototherapy treatment for especially thick and/or extensive plaque psoriasis it should usually only be considered in patients with chronic plaque psoriasis, if NB-UVB has not been adequately effective.
- PUVA is the first-line treatment for plaque-stage cutaneous T-cell lymphoma (CTCL).
- PUVA using topical or oral psoralen should be considered as a treatment for palmoplantar psoriasis.
- PUVA using oral psoralen should be considered as a treatment for palmoplantar pustulosis.

In 2007, the National Institute for Clinical Excellence (NICE) (United Kingdom) published a guidance document for the treatment of atopic eczema in children up to age 12 years. The clinical trials revealed limited evidence of the effectiveness of phototherapy in the treatment of children and possible serious adverse effects. The Guidance Development Group concluded that phototherapy should only be considered “for the treatment of severe atopic eczema in children when other management options have failed or are inappropriate and where there is a significant negative impact on quality of life.” Laser therapy was not discussed as a treatment option.

In a 2012 guideline for the treatment of alopecia areata, the British Association of Dermatologists (BAD) stated that they cannot recommend the use of PUVA due to potentially serious side-effects and inadequate evidence.

The National Institute for Health and Care Excellence (NICE) 2012 (updated 2017) included phototherapy (broad or narrow-band UVB and PUVA) as a treatment option for psoriasis in their guideline for management of this condition. NICE recommended phototherapy for the treatment of plaque or guttate-pattern psoriasis that cannot

be controlled with topical therapy. PUVA can be considered for the treatment of palmoplantar pustulosis. NICE stated that phototherapy should not be routinely used as a maintenance therapy.

The European Dermatology Forum issued a consensus guideline in collaboration with the Vitiligo European Task Force, European Academy of Dermatology and Venereology, and the Union Europe'enne des Me'decins Spe'cialistes on the treatment of Vitiligo stating that PUVA photochemotherapy for generalized vitiligo is recommended as a second-line therapy. Narrowband UVB is recommended as a first-line treatment as it has an advantage over PUVA in that it has a higher efficacy and smaller short- and long-term risks. The guideline further states that excimer laser therapy is a good option for localized vitiligo (Taieb, et al., 2013).

In a national clinical guideline on the management of psoriasis, the Scottish Intercollegiate Guidelines Network (2010) stated that the use of PUVA, narrowband UVB, and broadband UVB were all effective in treating and clearing psoriasis, however the use of broadband UVB is not recommended since studies have found that it's short wavelengths are more likely to cause burning of the skin. Narrowband UVB, administered three times per week, is recommended in patients who fail to respond to topical therapy and PUVA should be considered in patients who fail narrowband UVB. Narrowband UVB should be considered in the home setting for patients who are unable to attend outpatient therapy.

The European Organization for Research and Treatment for Cancer (EORTC) (Belgium) (Trautinger, et al., 2006; updated 2017) consensus recommendations for the treatment of stages IA, IB and IIA mycosis fungoides and Sezary syndrome included PUVA as a treatment option for these conditions. PUVA and UVB were listed as agents that can be used after remission has been achieved for MF and SS.

Medicare Coverage Determinations

	Contractor	Policy Name/Number	Revision Effective Date
NCD	National	Treatment of Psoriasis (250.1)	No Effective Date
LCD	CGS	Outpatient Physical and Occupational Therapy Services (L34049)	5/27/2021
LCD	NGS	Outpatient Physical and Occupational Therapy Services (L33631)	1/1/2020
LCD	Palmetto	Outpatient Physical Therapy (L34428)	3/25/2021
LCD	First Coast	Therapy and Rehabilitation Services (L33413)	10/1/2019
LCD	Novitas	Therapy and Rehabilitation Services (PT, OT) (L35036)	11/14/2019

Note: Please review the current Medicare Policy for the most up-to-date information.

Coding/Billing Information

- Note:** 1) This list of codes may not be all-inclusive.
 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Office-Based Phototherapy and Photochemotherapy

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
96900	Actinotherapy (ultraviolet light)
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B
96912	Photochemotherapy; psoralens and ultraviolet A (PUVA)

CPT®* Codes	Description
96913	Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)

Office-Based Excimer Laser Therapy

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

CPT®* Codes	Description
96920	Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm
96921	Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm
96922	Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm

Home Phototherapy Devices

Considered Medically Necessary when criteria in the applicable policy statements listed above are met:

HCPCS Codes	Description
E0691	Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 square feet or less
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 foot panel
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 foot panel

Considered Specifically Excluded Under Some Benefit Plans:

HCPCS Codes	Description
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet, includes bulbs/lamps, timer and eye protection

***Current Procedural Terminology (CPT®) ©2020 American Medical Association: Chicago, IL.**

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