

Medical Coverage Policy

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Phototherapy, Photochemotherapy, Excimer Laser, Dermabrasion and Chemical Peels for Dermatologic Conditions

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Related Coverage Resources

Extracorporeal Photopheresis Gender Dysphoria Treatment Injectable Fillers Rosacea Procedures Scar Revision Topical Ruxolitinib

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide quidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s).

Page 1 of 35 Medical Coverage Policy: 0505 Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview

This Coverage Policy addresses office-based phototherapy, photochemotherapy, excimer laser therapy, dermabrasion, and chemical peel for dermatologic conditions in the adult and pediatric populations. 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.

Dermabrasion and chemical peels are skin resurfacing procedures that remove the epidermis and superficial layers of skin to allow re-epithelialization. Dermabrasion and /or chemical peels are types of treatment that are generally employed for treating large areas where lesions are multiple and diffuse.

Coverage Policy

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

Coverage for dermabrasion and/or chemical peel treatment varies across plans and may be subject to the provisions of a cosmetic and/or reconstructive surgery benefit and may be governed by state mandates. 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 therapy, systemic immunomodulators, systemic immunosuppresants) 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

Continued office-based phototherapy or photochemotherapy is considered medically necessary for the treatment of ANY of the above listed conditions when initial criteria are met and there is a beneficial clinical response to treatment.

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<u>Vitiligo</u>

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:
 - \circ $\,$ failure, intolerance or contraindication to a twelve 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 is considered medically necessary for the treatment of localized or generalized vitiligo when there is a beneficial clinical response to treatment.

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 not medically necessary in any setting for ANY other indication, including EACH of the following dermatologic conditions:

- alopecia areata
- 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)

Office-Based Excimer Laser Therapy

Plaque Psoriasis

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.

Continued office-based targeted excimer laser therapy (i.e., 308 nanometers [nm]) is considered medically necessary for the treatment of localized, plaque psoriasis when initial criteria are met and there is a beneficial clinical response to treatment.

<u>Vitiligo</u>

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 a twelve 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]) is considered medically necessary for the treatment of localized vitiligo when there is a beneficial clinical response to treatment.

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 not medically necessary in any setting for any other indication, including EACH of the following dermatologic conditions:

- alopecia areata
- 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
- onychomychosis
- palmoplantar eczema, acute
- pityriasis rosea
- prurigo nodularis
- psoriatic nail disease
- urticaria pigmentosa (cutaneous mastocytosis)

Dermabrasion

If coverage for dermabrasion is available, the following conditions of coverage apply:

Dermabrasion (CPT 15780, 15781, 15782) is considered medically necessary for the treatment of actinic keratoses when BOTH of the following criteria are met:

- lesions are diffuse (e.g., \geq 10 lesions) making targeted therapy impractical
- failure, contraindication or intolerance to one or more conventional field therapy treatments (e.g., topical 5-fluorouracil [5-FU, Efudex], topical diclofenac, photodynamic therapy [PDT], topical imiquimod [Aldara])

Each of the following is considered cosmetic and not covered or reimbursable:

- dermabrasion of ANY type (CPT 15780, 15781, 15782) for ANY other indication not listed above
- microdermabrasion or superficial dermabrasion (CPT 15783) for ANY indication

Chemical Peels

If coverage for chemical peel treatment is available, the following conditions of coverage apply:

Dermal chemical peels (CPT 15789, 15793) are considered medically necessary for the treatment of actinic keratoses when BOTH of the following criteria are met:

- lesions are diffuse (e.g., \geq 10 lesions) making targeted therapy impractical
- failure, contraindication or intolerance to one or more conventional field therapy treatments (e.g., topical 5-fluorouracil [5-FU, Efudex], topical diclofenac, photodynamic therapy [PDT], topical imiquimod [Aldara])

Each of the following is considered cosmetic and not covered or reimbursable:

- dermal chemical peels (CPT 15789, 15793) for ANY other indication not listed above
- epidermal chemical peels (CPT 15788, 15792) for ANY indication

Chemical Exfoliation

Chemical exfoliation (CPT 17360) for treatment of acne vulgaris or ANY other indication is considered cosmetic and not covered or reimbursable.

Health Equity Considerations

Health equity is the highest level of health for all people; health inequity is the avoidable difference in health status or distribution of health resources due to the social conditions in which people are born, grow, live, work, and age.

Social determinants of health are the conditions in the environment that affect a wide range of health, functioning, and quality of life outcomes and risks. Examples include safe housing, transportation, and neighborhoods; racism, discrimination and violence; education, job opportunities and income; access to nutritious foods and physical activity opportunities; access to clean air and water; and language and literacy skills.

According to the National Eczema Association (2022; updated 2023), 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.

General Background

Dermatologic conditions are a common human illness. For example, according to the American Academy of Dermatology Association (ADD) (2024), 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 ADD further states that in 2013 costs associated with treatment and lost productively 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.

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) (Valipour, l et al., 2020; 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; Pavlotsky, 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;

Page 6 of 35 Medical Coverage Policy: 0505 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).

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: 3 Series NeoLux (Daavlin Distributing Co., Bryan, OH) (K230382), 7 Series Phototherapy Device (Daavlin Distributing Co., Bryan, OH) (K212510), the Houva Phototherapy System with PhotoSense II[™] (National Biological Corporation, Inc., Beachwood, OH) (K041212), and the Psoria-Shield AURORA (Psoria-Shield, Utica, NY) (K192411).

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 therapy, 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 (Musters, et al., 2021; 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) (Davis, et al., 2024) gave a conditional recommendation for the use of phototherapy for adults with AD when the AD is more severe or refractory to topical treatment. The AAD stated that "wherever possible, use a light source that minimizes the potential for harm". Although AAD stated that home phototherapy can increase the accessibility of phototherapy, 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

Page 7 of 35 Medical Coverage Policy: 0505 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). A Cochrane systematic review (Valipour, et al., 2020) did not find evidence to challenge the roll of PUVA as a first-line treatment of MF based upon the results of five studies.

Professional Societies/Organizations: The National Cancer Institute (2024) 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[®]) (2023) lists phototherapy as treatment options for mycosis fungoides and Sezary syndrome recommending UVB and nbUVB for limited or localized skin involvement and UVB, nbUB, PUVA, or UVA1 for the treatment of generalized skin involvement. 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

Page 8 of 35 Medical Coverage Policy: 0505 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).

Page 9 of 35 Medical Coverage Policy: 0505 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 or 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:

• XTRAC XL Excimer Laser System (PhotoMedex, Inc. Carlsbad, CA) is approved for the treatment of psoriasis, vitiligo, leukoderma, and atopic dermatitis (K041943).

- 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 (K073066).
- 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" (K050080).
- 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 (K040062).
- XTRAC Momentum Excimer Laser System (Strata Skin Sciences, Inc., St. Petersburg, FL) is indicated for the treatment of psoriasis, vitiligo, atopic dermatitis, and leukoderma (K193478).

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; 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. Pruritis, 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, onychomychosis, 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 (Gupta, et al., 2021; Obeid, et al., 2020; Contreras-Ruiz, 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., 2008; Sezer, et al., 2007; Baltás, 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, updated 2022; Messenger, et al., 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, retrospective reviews, and a randomized controlled trial with small patient populations (n=3-18), short-term follow-ups (e.g., five weeks to six months), and heterogeneous treatment parameters. Outcomes varied depending on the type of alopecia and some patients had no response to therapy (Kianfar, et al., 2022; Gupta, et al., 2021; Alkhalifah, et al., 2010).

A meta-analysis completed by Gupta et. al. (2021) 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).

Page 12 of 35 Medical Coverage Policy: 0505 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], 2016; 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).

Page 13 of 35 Medical Coverage Policy: 0505 **Literature Review:** Evidence in the peer reviewed literature is limited to comparative and noncontrolled 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.

Literature Review: 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.

Generalized (Disseminated) Granuloma Annulare: Generalized granuloma annulare (GA) presents with numerous benign pruritic erythematous or skin-colored papules and plaques affecting, most often, the trunk and extremities that will spontaneously resolve over the course of a few years. The lesions range in size from a few millimeters to a few centimeters in diameter. In individuals with darker skin color, the lesions may present with hypo or hyperpigmentation. The exact cause of GA is unknown, and it can affect both children and adults. Skin biopsy if often required to confirm a diagnosis of generalized GA due to the variable characteristics of the lesions and potential overlap with other skin conditions. The decision to treat generalized GA is based upon the appearance of the lesions and the intractable pruritis associated with the condition. Although a standard of care for treatment does not exist, the preferred initial therapy to treat generalized GA is systemic therapy with hydroxychloroquine since widespread application of topical therapy can be challenging with numerous lesions. Other options include oral isotretinoin and dapsone. PUVA, UVB, nbUVB, UVA, and excimer laser have also been proposed for the treatment of generalized GA (Brodell, 2023; Brodell, 2021; Mukovozov, et. al., 2021).

Literature Review: The evidence published in the peer-reviewed literature for the treatment of generalized GA with phototherapy and photochemotherapy consists of case reports and small case series limited by small patient populations, short-term follow-up, and heterogeneity of study designs and treatment parameters. (Mukovozov, et al., 2022; Muylaert, et al., 2017; Cunningham, et al., 2016; Pavlovsky, et al., 2016; Yong, et al., 2016).

Mukovozov, et al. (2021) conducted a systematic review of thirty-one case series to evaluate the safety and efficacy of light and laser-based treatments for the treatment of localized and generalized GA. There were 336 participants (67.6% had generalized GA) in total ranging in age from 6–89 years of age with 74.6% being female. Cohort, cross-sectional, and case-controlled studies, and case series were considered for inclusion in the review if they evaluated the use of phototherapy (of any type) in individuals of any age diagnosed with GA (localized, generalized, or unspecified). The interventions evaluated in the review included: PUVA, photodynamic therapy, UVB/nbUVB/excimer laser, UVA, and lasers. Outcomes evaluated included complete resolution, partial resolution, and no response. However, these outcomes were not defined. The duration of follow-up was not specified. A synthesis of quantitative evidence was not possible due to heterogeneity of study design and patient characteristics. Overall, the studies were found to have a moderate risk of bias. PUVA was evaluated in 119 participants with generalized GA and found that 57%, 26%, and 17% achieved complete resolution, partial resolution, and no response, respectively. UVA1 was evaluated in 47 participants with generalized GA and found that 45%, 23%, and 32% achieved complete resolution, partial resolution, and no response, respectively. UVB/nbUVB was evaluated in 37 participants with generalized GA and found that 35%, 22%, and 43% achieved complete resolution, partial resolution, and no response, respectively. The mean time to achieve either complete or partial response was 2.1 and 2.2 months respectively for PUVA, 0.8 and 0.8 respectively for UVA1, and 3.1 and 2.4 months respectively for UVB/nbUVB/excimer. Mean time to response data was not categorized by GA subtype. Higher response rates were observed for localized GA compared to generalized GA. Author noted limitations of the review included: heterogeneity in study designs, patient populations, treatment interventions, and outcome measures preventing generalizability of the results; lack of high-level evidence, and small sample sizes. High quality studies with longer follow-up, larger samples sizes, focused patient populations and treatment parameters are needed to support the use of phototherapy and photochemotherapy in individuals with generalized GA.

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 (InGaAIP; 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

Page 15 of 35 Medical Coverage Policy: 0505 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.

Onychomychosis: 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 non-systemic 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).

Literature Review: 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

Page 16 of 35 Medical Coverage Policy: 0505 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.

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, 2021; 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

Page 17 of 35 Medical Coverage Policy: 0505 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, parthormone, 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.

Dermabrasion and Chemical Peels

Dermabrasion and/or chemical peels are established dermatological treatments for specific skin conditions and may be recommended for the treatment of precancerous skin lesions (i.e., actinic keratoses); however, in many cases these methods of treatment do not improve function and are employed for the improvement of personal appearance. Treatments intended to improve personal appearance or that do not improve functional deficits are considered cosmetic in nature.

Precursor squamous cell carcinoma (SCC) lesions include those that are precancerous (i.e., actinic keratoses [AK]) and lesions that are squamous cell carcinoma in situ (e.g., Bowens disease). According to National Comprehensive Cancer Network (NCCN) Guidelines[™] Basal Cell Skin Cancers (NCCN, 2024) and Squamous Cell Skin Cancers (NCCN, 2024), both lesion types can lead to invasive squamous cell carcinoma and potential metastasis; therefore, early treatment is recommended. While there are a variety of techniques available with comparable effectiveness for precancer-type lesions, chemical peels and dermabrasion may be considered accepted treatments for actinic keratoses. Dermabrasion and chemical peels are not listed in the NCCN guidelines as accepted treatment for squamous cell carcinoma in situ (i.e., Bowen's disease). There are no precursor lesions for basal cell carcinoma.

Dermabrasion: Dermabrasion is a surgical procedure that resurfaces the texture of the skin by removing its top layer using a mechanical instrument (such as a high-speed rotary abrasive wheel) to remove the layers of skin. Dermabrasion is also referred to as abrasion, salabrasion, microdermabrasion, dermaplaning or sanding the skin. Laser abrasion (Tunable Dye, CO² and Ruby lasers) and chemobrasion (phenol, trichloroacetic acid and glycolic acid) are modalities of treatment that are used in place of conventional dermabrasion.

Dermabrasion, most often performed for the purpose of removing acne scars, tattoos or fine wrinkles, is performed in an office setting using a local anesthetic. Depending on the severity of the lesion and area being treated, a second treatment may be required for complete results. Following treatment, the individual can expect discoloration and scabbing to occur, which will last for five to seven days. Discoloration and swelling can last for two to three months while the area is healing. Scarring after the skin has healed is rare.

Dermabrasion has proven effective in treating multiple recalcitrant actinic keratoses (AK) lesions in cases where numerous AK lesions (e.g., more than 10) have been documented and where lesions are diffuse with severe actinic damage. AK lesions are precancerous skin lesions that occur on the epidermis (outer layer of skin) and result from long-term exposure to the sun. The condition is also commonly referred to as solar keratosis, senile keratosis, senile hyperkeratosis, keratoma senile and keratosis senilis. Microscopically, AK lesions show varying degrees of atypia and abnormal maturation and may be further classified as atrophic, hyperkeratotic, bowenoid, acantholytic, lichenoid and pigmented (Gupta, 2012). AKs are the most commonly treated type of premalignant lesion and are considered precursor lesions to squamous cell carcinoma (SCC). In general, treatment of AK lesions is divided into lesion directed therapy or field therapy (Gupta, 2012). Lesion directed therapy targets a specific lesion. Field therapy is used to treat areas involving subclinical lesions and areas involving multiple clinical lesions making it impractical to treat each lesion separately. Topical field therapies that have proven effective for AK lesions include 5-fluorouracil, imiquimod, diclofenac, ingenol gel, photodynamic therapy, dermabrasion and chemical peels. Dermabrasion for other dermatological conditions is considered cosmetic.

Microdermabrasion is a non-invasive, non-surgical cosmetic procedure that can be performed either by a physician or in some cases, by individuals in a home setting. The noninvasive treatment exfoliates or removes the top layer of skin (i.e., stratum corneum) and is frequently performed to diminish the signs of aging. Dermabrasive procedures that resurface the superficial layer of skin, including but not limited to those used to reduce the signs of aging, are considered cosmetic.

Chemical Peel: A chemical peel, also referred to as chemexfoliation, involves the application of a chemical solution with the goal of producing controlled removal of layers of the epidermis and superficial dermis. Although used primarily on the face, chemical peels can be used on other areas such as the neck and hands. Chemical peel solutions damage the outer layers of the skin and stimulate collagen formation, resulting in dermal regeneration and improvement of the appearance of the skin. Categories of chemical peels include superficial, medium-depth and deep.

Superficial peels (epidermal peels) extend down to the stratum granulosum and papillary dermis. This type of chemical peel is recommended as an effective treatment for conditions which include, but are not limited to, mild photoaging, acne, and melasma. Alpha-hydroxy acids (AHAs), such as glycolic, lactic or fruit acid, are used in superficial peeling to rejuvenate and resurface sundamaged skin, soften the appearance of pores, treat fine wrinkles and reduce uneven pigmentation. Superficial chemical peels that affect the superficial layer of skin are considered cosmetic.

Dermal chemical peels may be either medium-depth or deep. Medium-depth and deep chemical peels penetrate deeper into the dermis. Medium-depth peels are used to treat moderate photoaging, actinic keratoses, pigmentary dyschromias and mild acne scarring. Trichloroacetic acid (TCA) with Jessner's solution or 70% glycolic acid is used for medium-depth peeling to treat surface wrinkles and sun-damaged skin. Phenol 88%, one of the strongest peels, may also be used as a medium-depth peel.

Deep chemical peels are used to penetrate further into the dermis and are often used to treat more severe photodamage, actinic keratosis, acne scars and pigmentary dyschromias. Baker's solution and 50% or greater TCA are solutions typically used in deep chemical peeling to diminish coarse facial wrinkles and correct pigment abnormalities.

Similar to dermabrasion, medium and deep chemical peels are a type of field therapy employed for treating recalcitrant AK when there are numerous lesions (e.g., more than 10) and other types of field therapy have not been effective. When used to treat other epidermal or dermal conditions, such as photo-aging, scarring, wrinkles or uneven pigmentation, chemical peels in the absence of a functional deficit are considered cosmetic and not medically necessary.

When used for the treatment of acne vulgaris, the clinical effectiveness of chemical peel treatments has not been firmly established (Zaenglein, et al., 2016). Some studies have suggested that superficial or epidermal peels using AHAs may have a comedolytic effect on comedonal acne lesions by loosening follicular impaction and may be appropriate for individuals with widespread lesions for whom standard treatment has failed. However, the clinical effectiveness of superficial peels in the overall management of patients with active acne has not been established through well-designed trials. Additionally, medium and deep chemical peels are not considered appropriate for active acne as they have been shown to exacerbate the inflammation associated with acne. As noted in guidelines of care for the management of acne vulgaris, the American Academy of Dermatology acknowledges that large, multicenter, doubleblinded control trials comparing chemical peels to placebo and comparing different types of chemical peels for the treatment of acne are lacking. Glycolic and salicylic acid peels may be used for the treatment of non-inflammatory acne (comedonal) although treatments require multiple applications and results are not long-lasting (Zaenglein, et al., 2016). According to the guidelines of care, chemical peels may result in mild improvement of comedonal acne, a recommendation based on inconsistent or limited quality patient-oriented evidence (B recommendation). Overall, the evidence available in the published, peer-reviewed scientific literature is insufficient and does not lend strong support to the clinical utility of any type of dermal chemical peel or chemical exfoliation in the treatment of acne vulgaris.

Cosmetic Indications

When performed solely for the purpose of altering appearance or self-esteem, or to treat psychological symptomatology or psychosocial complaints related to one's appearance, dermabrasion and chemical peels are considered cosmetic and not medically necessary. Examples of conditions for which dermabrasion and chemical peels are considered cosmetic include but are not limited to the following:

- > rhinophyma
- rosacea
- scar revision
- treatment of photo-aged skin
- treatment of uneven pigmentation
- treatment of rhytids (i.e., wrinkles)
- removal of tattoos

U.S. Food and Drug Administration (FDA): Some chemical peels may be prepared in an office setting and may involve the use of various chemical agents, including ingredients considered to be cosmetic. As a result, FDA approval or clearance may not be relevant.

Dermabrasion is considered a noninvasive surgical procedure and as such is not regulated by the FDA. However, devices, such as those used for microdermabrasion, are regulated by the FDA.

Professional Societies/Organizations:

Several professional societies/organizations, including but not limited to the American Society of Plastic Surgeons and the American Osteopathic College of Dermatology, provide information regarding treatments aimed at improving the appearance of various dermatological conditions. For most dermatological conditions, specific recommendations such as a formal guideline or a position statement could not be found.

The American Academy of Dermatology (2016) published guidelines of care for the management of acne vulgaris. Per the report, inconsistent or limited-quality patient-oriented evidence is present for the use of chemical peels. Existing studies note the need for multiple treatments and shortterm effects with only mild improvement in comedonal acne. They further acknowledge that large, multicenter, double-blinded control trials comparing peels to placebo and comparing different peels are lacking (Zaenglein, et al., 2016).

Guidelines issued by the National Comprehensive Cancer Network (NCCN) for squamous cell skin cancer (SCC) were updated in 2024. The presence of actinic keratoses (AK) increases an individual's risk for developing SCC. The guideline recommends aggressive treatment of AK and squamous carcinoma in situ lesions at first development as part of the identification and management of high-risk patients. Treatments for precancerous lesions (i.e., actinic keratosis): chemical peels (trichloracetic acid) and ablative skin resurfacing (laser, dermabrasion) have been proven effective for treatment. AK with an atypical clinical appearance, or that does not respond to appropriate therapy should be biopsied for histologic evaluation (NCCN, 2024).

Guidelines issued by the National Comprehensive Cancer Network (NCCN) for basal cell skin cancer treatment are dependent on risk stratification. Curettage and electrodesiccation (C&E) and surgical excision are the preferred treatments for low-risk basal cell skin cancers. Those with highrisk basal cell skin cancer are recommended to undergo surgical excision (e.g. Mohs surgery). If the patient is not a surgical candidate, radiation or systemic therapy is proposed (NCCN, 2024).

	Contractor	Determination Name/Number	Revision Effective Date
NCD	National	National Coverage Determination (NCD) for Treatment of Psoriasis (250.1)	Long standing; no date
NCD	National	Treatment of Actinic Keratosis (250.4)	11/26/2001
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)	3/25/20201
LCD	Palmetto	Cosmetic and Reconstructive Surgery (L33428)	7/29/2021
LCD	First Coast	Therapy and Rehabilitation Services (L33413)	10/1/2019
LCD	First Coast	Cosmetic and Reconstructive Surgery (L38914)	5/13/2022
LCD	Novitas	Therapy and Rehabilitation Services (PT, OT) (L35036)	11/14/2019
LCD	Novitas	Cosmetic and Reconstructive Surgery (L35090)	5/13/2022
LCD	Wisconsin Physicians	Cosmetic and Reconstructive Surgery (L39051)	11/14/2021

Medicare Coverage Determinations

	Contractor	Determination Name/Number	Revision Effective Date
LCD	Noridian	Plastic Surgery (L35163 and L37020)	10/1/2019
Note: DI	Note: Place review the surrent Medicare Palicy for the meet up to date information		

Note: Please review the current Medicare Policy for the most up-to-date information. (NCD = National Coverage Determination; LCD = Local Coverage Determination)

Coding Information

Notes:

- 1. This list of codes may not be all-inclusive since the American Medical Association (AMA) and Centers for Medicare & Medicaid Services (CMS) code updates may occur more frequently than policy updates.
- 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®*	Description
Codes	
96900	Actinotherapy (ultraviolet light)
96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B
96912	Photochemotherapy; psoralens and ultraviolet A (PUVA)
96913	Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)

Office-Based Excimer Laser Therapy

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

CPT [®] *	Description
Codes	
96920	Excimer laser treatment for psoriasis; total area less than 250 sq cm
96921	Excimer laser treatment for psoriasis; 250 sq cm to 500 sq cm
96922	Excimer laser treatment for psoriasis; over 500 sq cm

Dermabrasion

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

CPT®* Codes	Description
15780	Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)
15781	Dermabrasion; segmental, face
15782	Dermabrasion; regional, other than face

ICD-10- CM Diagnosis Codes	Description
L57.0	Actinic keratosis

Not Covered or Reimbursable:

ICD-10- CM Diagnosis Codes	Description
	All other codes

Superficial/Microdermabrasion

Not Covered or Reimbursable:

CPT®* Codes	Description
15783	Dermabrasion; superficial, any site (eg, tattoo removal)

ICD-10- CM Diagnosis Codes	Description
	All codes

Chemical Peels

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

CPT®* Codes	Description
15789	Chemical peel, facial; dermal
15793	Chemical peel, nonfacial; dermal

ICD-10- CM Diagnosis Codes	Description
L57.0	Actinic keratosis

Not Covered or Reimbursable:

ICD-10- CM Diagnosis Codes	Description
	All other codes

Epidermal Chemical Peels

Not Covered or Reimbursable:

CPT®* Codes	Description
15788	Chemical peel, facial; epidermal
15792	Chemical peel, nonfacial; epidermal

ICD-10- CM Diagnosis Codes	Description
	All codes

Chemical Exfoliation

Not Covered or Reimbursable:

CPT®* Codes	Description
17360	Chemical exfoliation for acne (eg, acne paste, acid)
ICD-10- CM Diagnosis Codes	Description
	All codes

*Current Procedural Terminology (CPT®) ©2023 American Medical Association: Chicago, IL.

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Type of Revision	Summary of Changes	Date
Focused review	 Content from CP 0505 Dermabrasion and Chemical Peels moved into this CP. Title change. Revised policy statements for: dermabrasion for any other indication, microdermabrasion or superficial dermabrasion, dermal chemical peels, and epidermal chemical peels. 	11/12/2023
Annual Review	 Added policy statements for contituation of coverage for phototherapy, photochemotherapy, and excimer laser therapy. Revised the policy statements for phototherapy, photochemotherapy, and excimer laser therapy for excimer laser therapy. Removed the policy statement for home phototherapy devices. 	7/15/2024

Revision Details

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