HEALTH PLANS
UNIVERSITY OF UTAH

Medical Policy

Phototherapy, Photochemotherapy or PUVA, and Excimer Laser Therapy for Dermatologic Conditions

Policy MP-048

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Disclaimer:

1. Policies are subject to change in accordance with State and Federal notice requirements.
2. Policies outline coverage determinations for U of U Health Plans Commercial, Healthy U (Medicaid) and Advantage U (Medicare) plans. Refer to the "Policy" section for more information.
3. This Medical Policy does not guarantee coverage or payment of the service. The service must be a benefit in the member's plan and the member must be eligible for coverage at the time of service. Additional payment guidelines may be applied that are not included in this policy.

Description:

Psoriasis was historically viewed as a disease of skin hyperproliferation, but it is now known that psoriasis is a complex immune-mediated disease. The condition causes thick, pink, scaly areas to develop. When they form large areas over the body, this is called plaque psoriasis. This is considered chronic and not curable, though it can go into remission. It may appear in a single patch or join together and vary in size.

Atopic dermatitis (eczema) is a condition that causes pink, itchy rashes. It usually starts in childhood, but can occur at any age. Atopic dermatitis may get better with age, but is often a chronic condition. It may be accompanied by asthma or hay fever. No cure has been found for atopic dermatitis. Topical treatments and self-care measures can relieve itching and prevent new outbreaks. For example, gentle soaps, moisturizers, and applying medicated creams or ointments can help control symptoms.

Actinic keratoses (AKs or solar keratoses) are sun-induced skin lesions which may evolve into skin cancer. Cryotherapy is commonly used to treat individual lesions. However, this treatment fails to address neighboring sun-damaged skin. "Field therapy" is recommended as a more effective treatment for more extensive sun damage. This therapy involves application of topical agents such as 5-flourouricil, imiquimod or photodynamic therapy using 5-aminolevulinic acid (ALA), or methyl aminolevulinate (MAL) as the skin sensitizers. These agents are preferentially taken up by the abnormal cells and the light therapy leads to activation of the chemical inside the cell and cellular destruction.

One therapy which has shown some effectiveness in both psoriasis and atopic dermatitis is phototherapy. Phototherapy (also called light therapy and actinotherapy) involves exposing the skin to wavelengths of ultraviolet A light (UVA) or ultraviolet B light (UVB), under the supervision of a health care provider. This is done for a set length of time on a regular schedule and may be done in a doctor's office, clinic, or at home. Phototherapy can be delivered in different ways. It can encompass the use of visible light, photodynamic therapy, photothermolysis, and laser therapy. The beneficial effect of using light therapy for the treatment of psoriasis is attributed primarily to UVB, which penetrates the skin and slows the growth of affected skin cells.

Psoralen plus ultraviolet A (PUVA) is a type of photochemotherapy that uses radiation and the administration of psoralens, a class of phototoxic plant-derived compounds, with an exposure to UVA by using sunlight or artificial light. Psoralens makes the skin more sensitive and responsive to this wavelength of light. They may be taken orally, applied topically, or patients can soak in a bath of Psoralens solution. PUVA has most commonly been used to treat severe psoriasis, for which there is no generally accepted first-line treatment. However, the requirement of systemic exposure and the higher risk of adverse reactions (including a higher carcinogenic risk) have generally limited PUVA therapy to patients with more severe cases. Potential long-term effects include photo-aging and skin cancer, particularly squamous cell carcinoma (SCC) and possibly malignant melanoma.

Excimer lasers emit a narrow beam of UVB light, from a handheld unit, which results in a much higher concentration of UVB exposure than in the standard phototherapy unit. The use of excimer laser can reduce the harmful effects of UV radiation by limiting the number of exposures needed and treating only the affected areas of the body.

Policy Statement and Criteria

1. Commercial Plans

U of U Health Plans considers office-based or home phototherapy (e.g., Actinotherapy, type A ultraviolet (UVA) radiation; type B ultraviolet (UVB) radiation; and combination UVA/UVB) and photochemotherapy (e.g., psoralens (P) and UVA, known as PUVA and combinations of P/UVA/UVB) medically necessary when there is failure, intolerance, or contraindication to conventional medical management* for the following dermatological conditions:

A. Connective tissue diseases involving the skin (e.g., cutaneous graft vs. host disease [GVHD], localized scleroderma, lupus erythematosus)

B. Cutaneous T-cell lymphoma (CTCL) (e.g., mycosis fungoides)

C. Lichen planus

D. Photodermatoses (e.g., polymorphic light eruption, actinic prurigo, chronic actinic dermatitis)

E. Psoriasis

F. Urticaria pigmentosa/systemic mastocytosis

G. Prurigo nodularis recalcitrant to treatment with topical and intralesional high potency steroids

H. Atopic dermatitis (i.e., atopic eczema) if the following criteria are met:

    i. Involvement is estimated to be >10% of the body surface area (BSA) AND one of the following:

        a) Eczema Area and Severity Index (EASI) score >16

        b) Investigators Static Global Assessment (ISGA) > 3

        c) Patient-Oriented Eczema Measure (POEM) > 8

        d) Scoring Atopic Dermatitis (SCORAD) index >15

**Conventional medical management consists of topical corticosteroids (ointment or creams), diet restrictions or retinoids as appropriate to the condition, or immunosuppressants such as calcineurin inhibitors.*

U of U Health Plans does NOT cover phototherapy, photochemotherapy or Photodynamic therapy as a treatment of rosacea or as a technique of skin rejuvenation, hair removal, or other cosmetic indications as cosmetic therapies are a plan exclusion.

U of U Health Plans does NOT cover phototherapy and photochemotherapy for any other diagnosis/condition not listed above including vitiligo and alopecia areata as they are considered experimental, investigational, unproven or not medically necessary.

U of U Health Plans covers photodynamic therapy for the treatment of non-hyperkeratotic actinic keratoses that are located on the face and/or scalp.

U of U Health Plans does NOT cover photodynamic therapy for the treatment of other dermatologic applications, including but not limited to, acne vulgaris, non-superficial basal cell carcinomas, hidradenitis suppurativa, or mycoses, due to the lack of scientific evidence demonstrating improved health outcomes.

U of U considers office-based targeted excimer laser therapy medically necessary for the treatment of localized, plaque psoriasis when it is refractory to conservative treatment with topical agents and/or standard phototherapy.

U of U Health Plans does NOT cover targeted excimer laser therapy (in any setting) for any other diagnosis/condition as it is considered cosmetic, experimental, investigational, unproven or not medically necessary.

U of U Health Plans considers Ultraviolet A (UVA) phototherapy in the home setting not medically necessary.

U of U Health Plans does NOT cover the use of a tanning bed/unit for any reason in any setting as it is considered not medically necessary.

2. **Medicaid Plans**
   Medicaid Plans will follow the commercial guidelines as listed above.

3. **Medicare Plans**
   Coverage is determined by the Centers for Medicare and Medicaid Services (CMS); if a coverage determination has not been adopted by CMS and InterQual criteria are not available, the U of U Health Plans Commercial criteria will apply. For the most up-to-date Medicare policies and coverage, please visit their search website at: http://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx?from2=search1.asp& or the manual website

Clinical Rationale

A significant body of evidence exists supporting the use of phototherapy for moderate-severe psoriasis and moderate to severe atopic dermatitis.

Psoriasis Hayes completed a Technology Brief on home UVB phototherapy for psoriasis in 2015. The authors noted that even though there is a low quality overall body of evidence, data suggests home UVB treatment of moderate to severe psoriasis is effective and well tolerated. Patient adherence to the home regimen was generally high and there were no major safety issues identified. In addition, patients were very satisfied with the convenience and outcomes from using home UVB treatments.

In 2019, a joint statement from the American Academy of Dermatology (AAD) and National Psoriasis Foundation (NPF) made the following statement "Although the entire UVB spectrum was used in initial UVB-based phototherapy (broadband UVB; BB-UVB), action spectrum studies have since determined that wavelengths between 304 and 313 nm produce the most therapeutic effect in clearing psoriatic plaques, whereas wavelengths from 290 to 300 nm, in fact, have very little benefit and mostly contribute to the development of sunburn. This revelation led to the development of a more precise treatment termed NB-UVB, which has now been used for many years with great efficacy. Further variations of UVB administration have been developed over the years and are being utilized and further investigated today, including various lasers, light-emitting diode lights, and combinations with other medications/preparations. Even visible light (400-700 nm) has been explored as a treatment for psoriasis".

The National Institute for Health and Care Excellence (NICE) 2012 (updated in 2017) included phototherapy (broad or narrow-band) UVB and PUVA as a treatment option for psoriasis. The guidelines suggest people with plague or guttate-pattern psoriasis that cannot be controlled with topical therapy, use phototherapy. To treat palmoplantar pustulosis consider psoralen (oral or topical) with local PUVA irradiation. However, when considering PUVA for psoriasis (plaque type or localized palmoplantar

pustulosis) discuss other treatment options and associated risk of increased skin cancer. NICE also stated that phototherapy should not be used routinely as maintenance therapy.

Atopic dermatitis The AAD (2014) recommended phototherapy under the guidance of a physician, as a second line of treatment for atopic dermatitis (AD), only after failure of the first line of therapy (emollients, topical steroids, and topical calcineurin inhibitors). Phototherapy may be used as maintenance therapy in patients with chronic disease. The light modality, dosing and scheduling is based on various factors, such as cost, phototherapy technique, patient skin type, skin cancer history, use of photosensitizing medication, minimal erythema dose (MED), and/or Fitzpatrick skin type. Although AAD stated that home phototherapy under the direction of a physician may be considered for a subset of patients who are unable to go to an office setting, they note that there are no studies that document the safety and efficacy of home phototherapy, or compare home therapy to in-office phototherapy outcomes for AD. Due to the lack of evidence, laser therapy is not a recommended treatment modality for atopic dermatitis.

Actinic Keratosis (AKs) According to the AAD (2019), to effectively treat AKs, you might be prescribed procedures, medications, or both. The most common form of treatment is cryotherapy, usually used if there are only a few visible AKs; to treat multiple AKs including ones you can't see yet, medication therapy that you apply to the skin may be used; shave excision and curettage is recommended for extremely thick AK's, that may or have not responded to cryotherapy or medication therapy; chemical peel or dermabrasion may be used for larger affected areas; and photodynamic therapy (PDT) is used for patients whose AKs return after treatments or who continue to produce new AKs.

A 2019 randomized trial (Jansen, et. al.) investigated four frequently used treatment approaches for multiple Aks in a continuous area. A total of 624 patients were randomly assigned treatment with 5% fluorouracil cream, 5% imiquimod cream, methyl aminolevulinate photodynamic therapy (MAL-PDT), or 0.015% ingenol mebutate gel from November 2014 through March 2017. After treatment ended, patients were tracked at the 12 month mark. The cumulative probability of remaining free from treatment failure was significantly higher among patients who received fluorouracil (74.7%; 95% confidence interval [CI], 66.8 to 81.0) than among those who received imiquimod (53.9%; 95% CI, 45.4 to 61.6), MAL-PDT (37.7%; 95% CI, 30.0 to 45.3), or ingenol mebutate (28.9%; 95% CI, 21.8 to 36.3). As compared with fluorouracil, the hazard ratio for treatment failure was 2.03 (95% CI, 1.36 to 3.04) with imiquimod, 2.73 (95% CI, 1.87 to 3.99) with MAL-PDT, and 3.33 (95% CI, 2.29 to 4.85) with ingenol mebutate ($P \leq 0.001$ for all comparisons). The authors concluded that 5% Fluorouracil cream was the most effective treatment in patients with multiple Aks on the head at 12 months after treatment ended.

In 2014, a systematic review and meta-analysis (Patel et. Al.) compared the effectiveness of PDT and cryotherapy for the treatment of Aks. The meta-analysis consisted of 641 participants, with a total of 2174 Aks treated with cryotherapy and 2170 Aks treated with PDT. Compared with cryotherapy, the pooled relative risk for the meta-analysis for complete response (lesion clearance) was 1.14 (95% CI, 1.11-1.18) at 3 months after treatment. Due to the lack of studies limited conclusions were made regarding treatment of AK's in areas other than the head and scalp. In conclusion, PDT has a 14% better chance of complete lesion clearance at 3 months for thin Aks on the face and scalp compared to cryotherapy.

Another systematic review and meta-analysis (Gupta, et. Al., 2012) assessed the effects of topical, oral, mechanical, and chemical interventions for the treatment of Aks. A total of 83 RTCs which included 10,036 patients were included. The RCTs covered 18 topical treatments, 1 oral treatment, 2 mechanical interventions, and 3 chemical interventions, including photodynamic therapy (PDT). The primary outcome significantly favored 4 field-directed treatments: 3% diclofenac in 2.5% hyaluronic acid (RR 2.46, 95% CI 1.66 to 3.66), 0.5% 5-fluorouracil (RR 8.86, 95% CI: 3.67 to 21.44), 5% imiquimod (RR 7.70,

95% CI 4.63 to 12.79), and 0.025% to 0.05% ingenol mebutate (RR 4.50, 95% CI 2.61 to 7.74) and PDT with the following photosensitizers: 3% diclofenac in 2.5% hyaluronic acid (RR 2.46, 95% CI 1.66 to 3.66), 0.5% 5-fluorouracil (RR 8.86, 95% CI: 3.67 to 21.44), 5% imiquimod (RR 7.70, 95% CI 4.63 to 12.79), and 0.025% to 0.05% ingenol mebutate (RR 4.50, 95% CI 2.61 to 7.74). The authors concluded that for individual lesions, treatment with PDT appears more effective and has a better cosmetic outcome than cryotherapy. For field-directed treatments, diclofenac, 5-fluorouracil, imiquimod, and ingenol mebutate are good options associated with different side-effects and cosmetic results. Thus, the choice of treatment option for Aks depends on the number of lesions, individual's desired results, and tolerance to the treatments. However, more studies for direct comparisons between these treatments are needed to determine the best therapeutic approach.

Other Conditions In 2016, a retrospective observational study (Brazzelli et. Al.) analyzed patients affected by cutaneous mastocytosis (CM) and indolent systemic mastocytosis (ISM) treated with phototherapy/ photochemotherapy (PUVA or NB-UVB). Urticaria pigmentosa and systemic mastocytosis are rare and chronic conditions for which there are few effective treatments. Clinical studies, though small, have shown impressive results for phototherapy with an excellent safety profile. Furthermore, phototherapy is a well-established and efficacious treatment for a wide range of other skin conditions such as psoriasis and atopic dermatitis. It has been used safely for decades with fewer side-effects and adverse events than systemic medication, and better efficacy when compared to topical medications. Clinical research has shown that home phototherapy in particular is cost-effective, safe and efficacious for the long-term management of dermatoses. For patient who have failed systemic treatment with antihistamines, both in-office and home phototherapy for long-term management would be safe and appropriate. This treatment is consistent with the current standard of care for the treatment of refractory urticaria pigmentosa and systemic mastocytosis.

Wang et. Al., conducted a Cochrane systematic review in 2017 of RCTs evaluating phototherapy for the treatment of foot ulcers in adult diabetics. The review included 8 trials with 316 participants. The studies compared phototherapy with sham phototherapy, no phototherapy, or other physical therapy modalities; different forms of phototherapy; or 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. The quality of the evidence was considered low due to small sample sizes, methodological flaws and unclear or high risk of bias. The authors concluded that in order to confirm whether phototherapy is an effective treatment option for foot ulcers in people with diabetes, large, well-designed randomized controlled trials are needed.

Another systematic review (Simonsen et. Al., 2017) assessed literature for treatment options in patients with uremic pruritus. This review of 44 RCTs included 39 different treatments (gabapentin, pregabalin, mast cell stabilizers, phototherapy, hemodialysis modifications, and multiple other systemic and topical treatments) and evaluated UV-B to UV-A therapy and narrow-band UVB. Dosages varied based on the patient's skin characteristics. Using broadband UV-B indicated a significant benefit in favor of UV-B therapy over UV-A. However, comparing narrow-band UV-B to UV-A showed no statistically significant benefit. The authors concluded, with the exception of gabapentin, the current evidence for treatments of uremic pruritus is low. Therefore, large, simple, rigorous, multiarm RCTs are needed to support the effectiveness of phototherapy and other treatments in uremic pruritus.

As for tanning beds, the NPF, the AAD, the U.S. Food and Drug Administration (FDA) and the Centers for Disease Control and Prevention (CDC) do not support the use of tanning beds and sun lamps as a substitute for phototherapy (even with a prescription and under the supervision of a physician). The ultraviolet radiation from these devices can damage the skin, cause premature aging and increase the risk of skin cancer.

The National Cancer Institute (NCI) (2019) 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.

Applicable Coding

CPT Codes

96567 Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitive drug(s), per day

96573 Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day

96574 Debridement of premalignant hyperkeratotic lesion(s) (ie, targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day

96900 Actinotherapy (ultraviolet light)

96912 Photochemotherapy; psoralens and ultraviolet A (PUVA)

96913 Photochemotherapy (Goeckerman and/or PUVA) for severe photo-responsive dermatoses requiring at least 4-8 hours of care under direct supervision of the physician (includes application of medication and dressings)

96920 Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm

96921 Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm

96922 Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm

HCPCS Codes

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
E0694	Ultraviolet multidirectional light therapy system in 6 foot cabinet, includes bulbs/lamps, timer and eye protection
J7308	Aminolevulinic acid HCl for topical administration, 20%, single unit dosage form (354 mg)
J7309	Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 g
J7345	Aminolevulinic acid HCl for topical administration, 10% gel, 10 mg

Not Covered

96999	Unlisted special dermatological service or procedure *(may be used in laser therapy for vitiligo, since there is no specific code)*

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