Phototherapy For Dermatologic Conditions

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INSTRUCTIONS:

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### POLICY DESCRIPTION:

This policy describes the use of phototherapy for the treatment of certain skin disorders. Phototherapy includes type A ultraviolet (UVA) radiation; type B ultraviolet (UVB) phototherapy; and combination UVA/UVB phototherapy.

Photochemotherapy is the therapeutic use of radiation in combination with a photosensitizing chemical. It includes psoralens (P) and type A ultraviolet (UVA) radiation, known as PUVA photochemotherapy and combinations of P/UVA/UVB.

Treatment requires the patient to ingest, topically apply, or bathe in a medication called psoralen before being exposed to UVA rays. UVB phototherapy involves exposing the skin to an artificial UVB light source (either narrow or broad band). Typically, treatment lasts 3 to 5 days a week for two or three months. Treatment with these modalities may involve partial or whole-body exposure.

### COVERAGE RATIONALE / CLINICAL CONSIDERATIONS:

#### I. OFFICE-BASED PHOTOTHERAPY OR PHOTOCHEMOTHERAPY

Office-based phototherapy includes actinotherapy (type A ultraviolet (UVA) or type B ultraviolet (UVB) and combination UVA/UVB). Photochemotherapy includes psoralens (P) and UVA, known as PUVA, and combinations of P/UVA/UVB.

1. Office-based phototherapy or photochemotherapy may be considered **MEDICALLY NECESSARY** when there has been a failure, intolerance, or contraindication to treatment using conventional medical management with topical or systemic drug therapy for ANY ONE of the following dermatological conditions:
   - Atopic dermatitis/eczema
   - Cutaneous T-Cell lymphoma (CTCL), Mycosis fungoides (MF), and Sézary’s Disease
   - Lichen planus
   - Morphea and localized skin lesions associated with scleroderma
   - Parapsoriasis
   - Photodermatoses
   - Pityriasis lichenoides
   - Pruritic eruptions of Human Immunodeficiency Virus (HIV) infection
   - Psoriasis (moderate to severe comprising less than 20% body area)
   - Urticaria pigmentosa
   - Vitiligo (Leukoderma)

2. Targeted phototherapy using an UVB laser (e.g., Xenon-Chloride, Excimer laser) may be considered **MEDICALLY NECESSARY** when the above criterion and medical conditions for office-based phototherapy are present.

3. Office-based Goeckerman regimen (UVB treatment in conjunction with topically applied chemicals, e.g., tars) may be considered **MEDICALLY NECESSARY** for the following:
   - Psoriasis
Atopic dermatitis

4. Office-based phototherapy, photochemotherapy, or targeted phototherapy using an UVB laser (e.g., Xenon-Chloride, Excimer laser) is considered **EXPERIMENTAL AND INVESTIGATIONAL** for the following:
   - First-line treatment of mild psoriasis, atopic dermatitis, atopic eczema;
   - Treatment of generalized psoriasis or psoriatic arthritis;
   - All other dermatologic conditions and diagnoses, including but not limited to:
     - Acne vulgaris
     - Alopecia areata
     - Granuloma annulare
     - Hypertrichosis
     - Keloids
     - Rosacea
     - Warts
     - Acquired perforating dermatosis
     - Chemical or contact dermatitis
     - Cholestasis of pregnancy
     - Dermatographic urticaria (dermographism and dermatographism)
     - Graft-versus-host disease (GVHD)
     - Granuloma annulare
     - Hidradenitis suppurativa
     - Infectious keratitis
     - Lymphomatid papulosis
     - Lichen simplex chronicus
     - Papular urticarial
     - Progressive macular hypomelanosis
     - Pruritis
     - Scleroderma
     - Skin-hypo-pigmentation from scarring

II. PHOTOTHERAPY IN THE HOME SETTING

1. Phototherapy in the home setting, using a home UVB phototherapy unit (medical durable equipment), may be considered **MEDICALLY NECESSARY** when the above criterion for office-based phototherapy, and the following conditions are met:
   - Improvement has been demonstrated with the use of UV treatments in the physician’s office or clinic, AND
   - Patient is capable of operating the home phototherapy unit, staying within prescribed periods of exposure, and the unit is expected to be used frequently (e.g., 3 times per week) on a long-term basis.

2. Phototherapy in the home setting, using ultraviolet A (UVA/PUVA) light devices, is considered **INVESTIGATIONAL AND NOT MEDICALLY NECESSARY** for all indications as this is considered not proven to be safe for treatment in the home.
III. Tanning beds/units for home phototherapy of dermatologic conditions are considered **NOT MEDICALLY NECESSARY** for any reason and in any setting because they are not considered medical in nature, and as such, do not meet the standard definition of Durable Medical Equipment.

IV. Combination bathing in Dead Sea water and phototherapy (e.g., Balneo-Phototherapy) is considered **EXPERIMENTAL AND INVESTIGATIONAL**.

**Clinical Considerations:**

- Most studies reported that patients receiving narrow-band ultraviolet B (NB-UVB) treatment developed mild-to-moderate erythema and pruritus. Hypertrophic scarring, keratoacanthoma, lentigines within nevus depigmentus, after prolonged intense NB-UVB exposure have also been reported.
- Patients with a history of systemic diseases with a photosensitive component such lupus erythematosus or xeroderma pigmentosum should not be treated with phototherapy.
- Phototherapy may be contraindicated in patients with a history of arsenic intake, previous treatment with ionizing radiation therapy, immunosuppressive states (e.g., organ transplant recipient), and any medical conditions in which the patient cannot tolerate heat or is unable to stand in the light box for prolonged periods of time. However, in other immunosuppressive states (e.g., patients who are positive for human immunodeficiency virus or other photodermatosis such as polymorphous light eruption) phototherapy is not contraindicated and can be an effective therapy.
- Because cumulative doses of UV light are associated with an increased risk of skin cancer, UVB therapy may not be appropriate for patients with a history of melanoma or multiple nonmelanoma skin cancers. Patients with a history of nonmelanoma skin cancers should only be considered if all other therapeutic options have been exhausted. Patients who receive UV phototherapy may have a 1.4- to 8.6-fold increased risk in developing skin cancer and should therefore be carefully monitored after treatment. Patients should be informed of the benefits and risks of phototherapy versus the increased risks of skin cancer. A history of excess UV exposure, young age, skin types I and II, atypical nevi, and family history of nonmelanoma skin cancer or melanoma are relative contraindications to phototherapy. (Price and Kerr, 2009).
- Other relative contraindications include current or previous treatment with cyclosporine or systemic tacrolimus. Patients who are claustrophobic or unable to stand for minutes at a time are not good candidates for booth phototherapy.
- Treatment-specific acute side effects of PUVA include nausea, and gastrointestinal complaints, inherent to psoralen intake. Potential long-term complications of PUVA included increased risk of cataracts, photodamage, and secondary skin carcinomas or melanomas.
- Home phototherapy is currently used as a second-line treatment option for adult patients whose disease has not responded to topical therapies but who have positively responded to outpatient phototherapy, and who are likely to adhere to treatment. Home phototherapy is also targeted to patients whose ability to attend regular outpatient phototherapy is restricted (time restriction, distance from clinic).
**BACKGROUND:**

Phototherapy is an established treatment for skin disorders that uses ultraviolet light, alone or in combination with topical preparations or oral medications, to treat various skin conditions. UV therapy involves exposure of the individual's skin to ultraviolet A (UVA) or UVB radiation using a specialized light source. As an alternative to ultraviolet therapy alone, some individuals respond to the Goeckerman or modified Goeckerman treatment, which is comprised of coal tar dressings in combination with exposure to UVB light. Phototherapy is usually for patients who do not tolerate or are unresponsive to conventional medical management. Photochemotherapy is the use of a photosensitizing chemical, psoralen, plus UVA and is called PUVA. Therapy may involve exposure to UVA, UVB, or a combination of UVA, UVB and/or PUVA.

**Description of Ultraviolet Light**

Solar emissions include light, heat, and ultraviolet radiation. UV radiation is divided into UVA, UVB, and UVC. All three bands are classified as probable human carcinogen.

- Long wavelength UVA covers the range of 315-400 nm and 90% of this wavelength reaches the earth’s surface.
- Medium wavelength UVB covers the range of 280-315 nm, approximately 10% reaches the earth’s surface.
- Short wavelength UVC covers the range of 100-280 nm, all solar UVC is absorbed by the ozone layer.

Therapeutic use of UV light may be used alone or in combination with topical preparations or oral medications as an established treatment for various dermatologic conditions. UVA and UVB involve exposing the skin to an artificial light source for a set length of time on a regular schedule (e.g., 3 to 5 times per week, with a gradual incremental increase in the delivered dose). UVB penetrates the skin and slows growth of skin cells associated with psoriasis and other skin conditions. UVB can be categorized as narrow-band or wide-band, which refers to the range of wavelengths included in the UV light source. The wide-band delivers full spectrum UVB light, and the narrow-band delivers very narrow range of UV light spectrum. NB-UVB can be delivered with a light bulb or with hand held laser device. An alternative to UV alone is the Goeckerman or modified Goeckerman treatment, which is comprised of coal tar dressings and exposure to UVB light.

Non-therapeutic or cosmetic use of ultraviolet light is the use of a tanning bed. This device emits ultraviolet radiation (typically 95% UVA and 5% UVB) from fluorescent bulbs in the range of 12 to 28 100-watt lamps for home use or 24 to 60 100 to 200-watt lamps for salon use, used to produce a cosmetic tan.

**Whole Body Phototherapy with Light-Box**

UVB can be directed to the whole body or large sections of the body with light-box panels or light cabinets. Broadband UVB (BB-UVB) devices, which emit wavelengths from 290 to 320 nanometers (nm), have been largely replaced by NB-UVB devices. NB-UVB devices eliminate wavelengths below 296 nm. NB-UVB is more effective than BB-UVB and approaches PUVA in efficacy.

**Targeted Phototherapy**

Targeted phototherapy describes the use of ultraviolet light that can be focused on specific body areas or lesions to treat patients with psoriasis. Conventional phototherapeutic options for treatment of psoriasis include photochemotherapy with psoralen plus ultraviolet A (PUVA) and both broad and narrowband ultraviolet B (UVB). UVB therapy has been commonly used to treat patients with moderate to severe
psoriasis. While PUVA therapy is considered more effective than UVB, 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 severe recalcitrant psoriasis. UVB is typically directed to the whole body or large sections of the body with light panels or light cabinets, requiring multiple treatments given several times a week. Broadband UVB devices, which emit wavelengths from 290 to 320 nm have been largely replaced by narrowband UVB (NB-UVB) devices. NB-UVB devices eliminate wavelengths below 296 nm, which are considered erythmogenic and carcinogenic but not therapeutic. NB-UVB is more effective than BB-UVB and approaches PUVA in efficacy.

Original NB-UVB devices consisted of a Phillips TL-01 fluorescent bulb with a maximum wavelength (lambda max) at 311 nm. Xenon chloride (XeCl) lasers and lamps have been developed as targeted NB-UVB treatment devices. These devices generate monochromatic or very narrow band radiation with a lambda max of 308 nm.

**Home Phototherapy**
A home phototherapy unit can be used to treat various dermatologic conditions. These devices are designed solely for the medical treatment of skin diseases, and usually contain multiple fluorescent lights, which emit high intensity, long-wave ultraviolet light on specific wavelengths. Dermatologists prescribe the form of phototherapy, the frequency and duration of treatment (most commonly based on skin type), and the escalation of dose. The standard protocol for NB-UVB treatment is 3 treatments per week for 3 months. The dermatologist educates the patient about the proper and safe use of phototherapy equipment, and how to differentiate therapeutic response to phototherapy from adverse events (painless pink tint to skin versus redness and sunburn). Home phototherapy is currently used as a second-line treatment option for adult patients whose disease has not responded to topical therapies but who have positively responded to outpatient phototherapy, and who are likely to adhere to treatment. Home therapy is also targeted to patients whose ability to attend regular outpatient phototherapy is restricted (time restriction, distance from clinic).

**PUVA**
PUVA is generally considered more effective than targeted phototherapy for the treatment of psoriasis. However, the requirement of systemic exposure and the higher risk of adverse reactions (including a higher carcinogenic risk) have generally limited PUVA therapy to patients with more severe cases. UVA light is offered in combination with a light sensitizing agent, psoralens to treat different skin conditions including refractory psoriasis. Treatment requires the patient to ingest orally, apply topically, or bathe in a medication called psoralens prior to exposure to ultraviolet light. Studies of the mechanism of action of psoralens suggest that multiple phenomena occur when these substances are photoactivated. Interstrand cross-linking occurs in DNA, and lipid membranes and enzymes are oxidized by oxygen radicals. An increase in the activity of melanocytes also occurs. During the course of therapy, the patient will need to be assessed on a regular basis to determine the effectiveness of therapy and the development of side effects. These evaluations are essential to ensure that the exposure dose of radiation is kept to the minimum compatible with adequate control of disease. Therefore, PUVA is generally not recommended for home therapy.

**Balneo-phototherapy**
Balneo-phototherapy is a combination of bathing in Dead Sea water and prolonged exposure to UV light. Dead Sea water has a unique composition; containing 30% dissolved solids and a marked enhancement of ions. It is believed that the high salt concentration, and in particular the presence of magnesium ions, have
both anti-inflammatory and anti-proliferative actions. A course of therapy may involve 15-25 treatments over a span of four to six weeks. Although this type of therapy has been used in parts of Europe, there is only one center in the United States that offers Balneo-Phototherapy, the Mavena Derma Center, which is located near Chicago, IL. The majority of patients undergoing UV treatments are treated in the office or clinic with UVA, UVB, PUVA, Goeckerman regime, or laser treatment.

**Indications for Phototherapy and/or Photochemotherapy**

NB-UVB and BB-UVB are used for the treatment of various skin conditions for who do not tolerate or are unresponsive to conventional medical management, including psoriasis, atopic dermatitis, T-cell lymphoproliferative disorders such as parapsoriasis or mycosis fungoides (MF), polymorphic light eruption (PLE), solar urticaria or hydroa vacciniforme, pruritus, chronic urticaria, graft-versus-host disease, acquired perforating dermatosis, lichen planus, lichen simplex chronicus, lymphomatoid papulosis, generalized granuloma annulare, nummular dermatitis, pityriasis lichenoides chronic, pityriasis rosea, pityriasis rubra pilaris, pruritic folliculitis of pregnancy, seborrheic dermatitis, Schnitzler syndrome, and Sneddon-Wilkinson disease. Skin improvement is generally seen after 1 to 3 months involving 20 to 40 treatments. After complete remission (CR) is achieved, the frequency of therapy is tapered very slowly during the maintenance period and then discontinued. Patients may resume phototherapy to maintain skin clarity when lesions reappear. Because of an increased risk of skin cancer, skin typing or phototesting before treatment determines the appropriate radiation dose. This is important because, while high doses of UV light may result in faster clearing of the lesions, the normal skin surrounding a lesion cannot tolerate such exposure. Frequently multiple sessions over 3 or more months are often required to produce clearing of skin lesions. During UV light therapy, the individual needs to be assessed by a medical professional on a regular basis to determine the effectiveness of the therapy and to monitor for the development of side effects, such as "sun burn" and pruritus (itching), as well as skin cancer, photoaging, and liver or kidney disease.

- **Atopic Dermatitis (AD)**
  Atopic dermatitis (or eczema) is the most common of many types of eczema; a skin disease characterized by areas of severe itching, redness, scaling, and loss of the surface of the skin; when the eruption has been present for a prolonged time, chronic changes occur due to the constant scratching and rubbing. The etiology is unknown. It often manifests in childhood, before the age of 5, and can persist into adulthood. There are periods of remissions and exacerbations. The disease may be exacerbated by a number of factors, including temperature, humidity, infections, food, allergens, microbial agents, and psychological stress. Skin care, avoidance of substances that might irritate the skin, and ointments and creams (e.g., immunomodulators and corticosteroids) may be indicated. If these are ineffective, a physician might prescribe an oral corticosteroid or phototherapy (e.g., UVA, UVB, and/or PUVA). AD may have a significant impact on morbidity and quality of life (QOL) of affected individuals, including their caregivers and families.

- **Psoriasis**
  Psoriasis is a chronic inflammatory disorder of the skin that is characterized by patches, scaly plaques, and papules that are often painful or pruritic (itchy). The etiology of psoriasis is not fully understood. The pathology of psoriasis includes genetic, immunologic, and environmental factors. Plaque psoriasis is the most common form of psoriasis, affecting 80% to 90% of patients. Plaque psoriasis is characterized by well-defined plaques that vary in size from one to several centimeters, and may range
in severity from only a few plaques to plaques covering almost the entire body surface. Approximately 80% of patients with psoriasis have mild to moderate disease, and 20% have moderate to severe psoriasis (defined as affecting greater than 5% of body surface area or affecting crucial body areas such as the face, hands, feet, or genitals). Psoriasis has a negative impact on the overall quality of life of patients, and is linked with psychological distress. Treatment of psoriasis is aimed at decreasing psoriasis severity and the patient’s body surface area (BSA) covered by plaques. Therapies include patient education; topical agents (e.g., emollients, Vitamin D analogs, steroids, coal tar, salicylic acid); systemic drugs (e.g., methotrexate, acitretin); biologic agents (e.g., adalimumab, etanercept, infliximab); exposure to ultraviolet (UV) light; and exposure to PUVA (psolaren administered prior to UVA light therapy).

- **Acne Vulgaris**
  Acne vulgaris is the most common dermatologic conditions in the United States, accounting for more than 30% of all dermatology visits per year; more than 45 million Americans are afflicted with an estimated prevalence of 85% between ages 15 and 24 years. An estimated 70% to 96% of the population will suffer from acne at some point in their lifetimes. Neonatal acne affects up to 20% of individuals during the first few weeks of life, although the actual nature of these skin eruptions is questionable and may be due to follicular stimulation by maternal adrenal androgens. Acne vulgaris is more common and severe among men. Acne vulgaris is a self-limited disorder that affects teenagers and young adults, although 10% to 20% of adults may experience some form of the disorder. Studies show the prevalence of acne vulgaris is 12% in females and 3% in males over age 25 years. Acne vulgaris is an interaction of exogenous and endogenous factors. Exogenous factors may be trauma, application of topical anti-acne agents, occupational exposure to chemical compounds such as halogenated aromatic compounds, oral ingestion of medications such as vitamin B complex, chemotherapeutic agents, steroids, oral contraceptive pills, lithium, isoniazid, androgenic steroids, halogens, phenytoin, and phenobarbital. Endogenous factors may be hormonal imbalance leading to hyperandrogenism, endocrinologic disease conditions such as polycystic ovarian syndrome, Cushing’s syndrome, or genetic factors. The face is the most common site affected by acne vulgaris, but the back, chest, and shoulders may be also involved in some patients. Acne may present as inflammatory and noninflammatory lesions. The noninflammatory lesions may be closed comedone (whitehead) or an open comedone (blackhead). The inflammatory lesions may be papular, pustular, and nodular acne. The main complications of acne vulgaris are scarring, hyperpigmentation, post-inflammatory erythema, emotional, social, and psychological impairment, sometimes leading to low self-esteem and depression.

- **Cutaneous T-Cell Lymphomas (CTCL)**
  CTCLs are any of a group of T-cell non-Hodgkin lymphomas that begins in the skin as an itchy, red rash that can thicken or form a tumor. The most common types are mycosis fungoides and Sézary syndrome. Mycosis fungoides affects only the skin while Sézary syndrome, cancerous Tcell lymphocytes affect the skin and the peripheral blood. MF has three phases: patch, plaque, and tumor. Patch phase is flat, red and scaly, while plaque phase is thicker raised lesions, and tumor phase has larger lesions that can be shaped like a mushroom. Sézary syndrome is an advanced form of mycosis fungoides. Skin all over the body is reddened, itchy, peeling, and painful. There may also be patches, plaques, or tumors on the skin. Cancerous T-cells are found in the blood. The AAD states treatment depends on the type of CTCL, health of the patient, extent of disease, age and lifestyle. Treatments include creams and ointments to skin (e.g., cortisone, nitrogen mustard, and retinoids), oral medications (e.g.,
corticosteroids, retinoids, and methotrexate), phototherapy (UVB, NB-UVB, and PUVA), interferon, and radiation. The National Cancer Institute states treatment including PUVA and UVB produce remissions, however long-term remissions are uncommon, therefore most treatments are considered palliative.

- **Lichen Planus**

  Lichen Planus (LP) is a common inflammatory disease that affects the skin, the mouth, or even the genital area with small, uncomfortable, pink or purple spots that occur mainly on the wrists, shins, lower back and genitalia. The cause of LP is unknown; however most dermatologists believe it can be classified as an autoimmune disease. It can present as reddish-purple, flattopped bumps or white lacy appearance that may be very itchy. The AAD states there is no cure for LP and treatment is aimed at relieving itching and in improving the appearance of the rash until it goes away. Mild cases may be treated with topical corticosteroid creams, ointments, or other anti-inflammatory drugs. Severe cases of LP may require stronger medications such as cortisone taken internally or phototherapy.

- **Morphea (localized scleroderma)**

  Morphea is a disorder characterized by excessive collagen deposition leading to thickening of the dermis, subcutaneous tissues, or both.

- **Parapsoriasis**

  Parapsoriasis is a group of cutaneous diseases that can be characterized by scaly patches or slightly elevated papules and/or plaques that have a resemblance to psoriasis but are unrelated with respect to pathogenesis, histopathology, and response to treatment. Parapsoriasis may precede CTCL. Treatment is possible when limited to the skin, otherwise palliative. Topical treatments include steroids, nitrogen mustard, and PUVA. For advanced stages, chemotherapy and radiation is the most effective.

- **Photodermatoses**

  Photodermatoses refers to skin disorders induced or exacerbated by light. The most common type is polymorphic light eruption, with a high prevalence of up to 10-20% in the United States. The skin might appear as spots, blisters, plaques or eczema. The exact mechanism of the diverse skin reactions to light radiation remains unclear. Treatment options include avoiding the sun, using high SPF sunscreens, topical or oral steroids. Appropriate therapy for severe cases includes phototherapy.

- **Pityriasis lichenoides (PL)**

  Pityriasis lichenoides is an uncommon skin condition that is difficult to diagnose and treat. It has potential to progress to cutaneous lymphoma or an ulceronecrotic presentation, which carry a risk of mortality. PL presents as pityriasis lichenoides et varioliformis acuta (PLEVA), pityriasis lichenoides chronica (PLC), and febrile ulceronecrotic Mucha-Habermann disease (FUMHD). PLEVA presents as multiple, small, red papules on the skin that develops into polymorphic lesions, with periods of remissions and periods of hyper/hypopigmentation and varicella-like scars. PLC presents as small red to brown flat maculopapules with mica-like scale with long periods of remission. FUMHD presents as generalized eruption of purpuric and ulceronecrotic plaques with systemic involvement and a mortality rate of up to 25%. The treatments for PLEVA and PLC are phototherapy, systemic antibacterials and topical corticosteroids. The treatment for FUMHD is immunosuppressant and/or immunomodulating agents, narrow-band UVB and intensive supportive care.

- **Pruritic eruptions of HIV disease**

  Pruritus is the medical term for itching. HIV is acquired human immunodeficiency virus.
Psoriasis
Psoriasis is a chronic skin disease that appears as patches of raised red skin covered by flaky white buildup. The exact cause is unknown, but is thought to be due to an immunologic dysfunction. The most common is plaque psoriasis, which can appear on any skin surface, however the most frequent is elbows, knees, scalp, and trunk. The skin involvement can range from localized areas to generalized body involvement. The disease is lifelong and characterized by periods of remissions and exacerbations. Patients with mild disease have limited body surface area (BSA) involvement and may be treated with topical therapies. Although moderate and severe disease categories may overlap, patients with moderate to severe disease generally have greater than 5% affected BSA, and appropriate therapies include phototherapy or systemic therapy.

Urticaria Pigmentosa
Urticaria is the name of a type of pale, itchy, pink wheals on the skin that are common and are part of an allergic reaction. The AAD states it is not serious and does not usually require any treatment in most cases. However, it can be helpful to eliminate possible foods, drugs, infections, insect bites that could be the cause. A physician might prescribe oral antihistamines, topical steroids, and for systemic urticaria that persists, PUVA or other forms of treatment.

Vitiligo
Vitiligo is an acquired idiopathic dermatological disorder characterized by depigmentation of the skin and mucus membranes. It is characterized by depigmented macules, which have a predisposition to form larger lesions. These lesions may occur on the face, genitals, mucus membranes, hands, feet, and extensor or periorificial surfaces. It is a multifactorial disorder and triggered by factors such as trauma, sunburn, stress, and systemic illness. Several hypotheses explain the pathogenesis of vitiligo: autoimmune, neural, self-destructive, biochemical, genetic association, viral, and convergence theory.

REGULATORY STATUS:

1. **U.S. FOOD AND DRUG ADMINISTRATION (FDA):**
   Phototherapy is a procedure and therefore not subject to FDA regulation. However, the UVB devices used in this procedure are regulated by the FDA. A number of different phototherapy devices have been approved by the FDA. Several phototherapy devices received 510(k) approval and are classified as Class II phototherapy units. FDA 510(k) approval does not require data regarding clinical efficacy. Some of the phototherapy devices are UVB Light Source (Jordan Light) (Richmond Light Co. Inc.), LH-75T Phototherapy System (Lerner Medical Devices Inc.), Resolve™ UVB Phototherapy System (Allux Medical Inc.), SoladSolRx 500 Series (Solarc Systems Inc.), and the Houva II Phototherapy System with PhotoSense™ (National Biological Corp.) (FDA, 2010).

   Original NB-UVB devices consisted of a Phillips TL-01 fluorescent bulb with a maximum wavelength (lambda max) at 311 nm. Xenon chloride (XeCl) lasers and lamps have been developed as targeted NB-UVB treatment devices. These devices generate monochromatic or very narrow band radiation with a lambda max of 308 nm. In 1999, the XeCl excimer laser (Acculase/PhotoMedex, Inc.) received 510(k) clearance from the U.S. Food and Drug Administration (FDA) for the treatment of mild to moderate psoriasis. FDA 510(k) clearance has subsequently been obtained for a number of targeted UVB lamps and lasers, including, but not limited to the following:
XTRAC™ Excimer Laser System. Model AL7000, PhotoMedex, Inc.;
XTRAC Excimer Laser System. Model AL7000, PhotoMedex, Inc.;
XTRAC Excimer Laser System. Model AL7000, PhotoMedex, Inc.;
XTRAC XL™ Plus Excimer Laser System. Model AL7000, PhotoMedex, Inc.;
XTRAC XL2™ Excimer Laser System Model AL8000, PhotoMedex, Inc.;
VTRAC™ Excimer Lamp System, Targeted (localized), PhotoMedex, Inc.;
BClear™ Targeted PhotoClearing™ System lamp (Lumenis).

The indicated use of these devices is targeted UVB phototherapy for treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis, and leukoderma. In May 2005, the Excilite™ and Excilite µ™ phototherapy systems (Cynosure, Inc.) received 510(k) clearance for the indications of leukoderma, psoriasis, vitiligo, eczema, and seborrheic dermatitis.

2. CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS):
   No CMS National Coverage Determination (NCD) or Local Coverage Determination (LCD) was identified for phototherapy for the treatment of skin conditions.

3. MINNESOTA DEPARTMENT OF HUMAN SERVICES (DHS):
   **Covered Services**
   Ultraviolet light therapy systems are used for treatment of chronic skin conditions.
   Ultraviolet light B (UVB) therapy systems for use in the home may be considered medically necessary for treatment of severe psoriasis in recipients for whom topical or oral medication has failed or is contraindicated, but who have responded to phototherapy, and who meet one of the following criteria:
   - Unable to attend therapy in the clinic due to a medical condition or disability.
   - Require treatment more than 2 times weekly over a period of several months.
   - Lack access to treatment in the nearest appropriate clinic due to one-way travel time in excess of one hour.

   **Non-Covered Services**
   - Ultraviolet multidirectional light therapy systems are not covered because they are not proven to produce better outcomes than other systems and because they are not the least costly effective treatment for any condition.
   - Home ultraviolet light A (UVA) systems are not covered for any indication because they are not proven to be safe for treatment in the home.
   - Home ultraviolet light systems are considered investigative for conditions other than severe psoriasis.

   **Authorization**
   Authorization is always required for purchase, rental, or repair of ultraviolet light therapy systems. Documentation must include:
   - Recipient’s diagnosis, including the extent and severity of the disease
   - History of oral and topical medications, and why they have failed or are contraindicated
   - Response to phototherapy in a clinic setting
   - Specific reason why treatment in the home is requested rather than treatment in the clinic.
   - Evidence of the recipient or caregiver’s ability to safely and effectively use the equipment in the home.
CLINICAL EVIDENCE:

SUMMARY:
Phototherapy involves the exposure of the skin to non-ionizing radiation for treatment of dermatologic conditions. Photochemotherapy is the application of phototherapy in conjunction with a photosensitizing agent (e.g., psoralen). Different types of therapy include type A ultraviolet (UVA), broad band type B ultraviolet (UVB), narrowband UVB, UVA plus psoralen (e.g., PUVA), and various combinations of these. The peer-reviewed literature and professional society treatment guidelines support the efficacy and safety of the use of phototherapy and photochemotherapy for multiple dermatological conditions including eczema, connective tissue disease, cutaneous T-cell lymphoma including mycosis fungoides, photodermatoses, lichen planus, psoriasis and vitiligo.

The evidence suggests that home UVB therapy for psoriasis is effective and well tolerated, and that patients generally adhered to treatment. No major safety issues were reported. Acute side effects of home UVB phototherapy were generally mild, and included erythema, alopecia, increased photosensitivity, and occasional blistering. Although it may be likely that UVB treatment is linked with increased risk of skin cancer, there were no data reported on incidence of skin cancer or other long-term side effects.

Ultraviolet B (UVB) home phototherapy may be indicated in a subset of individuals who meet the criteria for office-based phototherapy and photochemotherapy, have gained benefit from office-based therapy, and the use of phototherapy is expected to be long-term.

There is a lack of evidence in the published peer-reviewed literature to support the therapeutic effectiveness of excimer laser therapy for the treatment of atopic dermatitis and home-use of ultraviolet A (UVA) phototherapy. Tanning beds are not considered medical devices and are not used to treat medical conditions.

APPLICABLE CODES:

The Current Procedural Terminology (CPT®) codes and HCPCS codes listed in this policy are for reference purposes only. Listing of a service or device code in this policy does not imply that the service described by this code is a covered or non-covered health service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other medical policies and coverage determination guidelines may apply.

<table>
<thead>
<tr>
<th>HCPCS Code</th>
<th>Description</th>
</tr>
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<tbody>
<tr>
<td>A4633</td>
<td>Replacement bulb/lamp for ultraviolet light therapy system, each</td>
</tr>
<tr>
<td>E0691</td>
<td>Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 square feet or less</td>
</tr>
<tr>
<td>E0692</td>
<td>Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; 4 foot panel</td>
</tr>
<tr>
<td>E0693</td>
<td>Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; 6 foot panel</td>
</tr>
<tr>
<td>E0694</td>
<td>Ultraviolet multidirectional light therapy system in six foot cabinet; includes bulbs/lamps, timer and eye protection</td>
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<table>
<thead>
<tr>
<th>ICD-9 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>202.10-202.18</td>
<td>Mycosis fungoides</td>
</tr>
<tr>
<td>571.0-571.9</td>
<td>Chronic liver disease and cirrhosis</td>
</tr>
<tr>
<td>582.0-582.9</td>
<td>Chronic glomerulonephritis</td>
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</tbody>
</table>
585.1-585.9 Chronic kidney disease (CKD)
691.8 Other atopic dermatitis and related conditions
692.0-692.6 Contact dermatitis and other eczema
692.9 Contact dermatitis and other eczema, unspecified cause
695.4 Lupus erythematosus
696.0-696.2 Psoriasis and similar disorders
697.0 Lichen planus
698.0-698.4 Pruritus and related conditions
698.8 Other specified pruritic conditions
701.0 Circumscribed scleroderma
706.0 Acne varioliformis
706.1 Other acne, blackhead, comedo
709.1 Vitiligo

<table>
<thead>
<tr>
<th>ICD-10 Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>K73.0-K73.9</td>
<td>Chronic hepatitis, not elsewhere classified</td>
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<tr>
<td>K74.0-K74.69</td>
<td>Cirrhosis and cirrhosis of liver</td>
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<tr>
<td>K75.0-K75.9</td>
<td>Other inflammatory liver disease</td>
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<tr>
<td>L20.0-L20.9</td>
<td>Atopic dermatitis</td>
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<tr>
<td>L29.0-L29.9</td>
<td>Pruritus</td>
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<tr>
<td>L40.0-L40.9</td>
<td>Psoriasis</td>
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<tr>
<td>L41.0</td>
<td>Pityriasis lichenoides et varioliformis acuta</td>
</tr>
<tr>
<td>L41.1</td>
<td>Pityriasis lichenoides chronic</td>
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<tr>
<td>N03.0-N03.9</td>
<td>Chronic nephritis syndrome</td>
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<tr>
<td>N18.1-N18.9</td>
<td>Chronic kidney disease (CKD)</td>
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<tr>
<th>CPT® Code</th>
<th>Description</th>
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<tbody>
<tr>
<td>96900</td>
<td>Actinotherapy (ultraviolet light)</td>
</tr>
<tr>
<td>96910</td>
<td>Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B</td>
</tr>
<tr>
<td>96912</td>
<td>Photochemotherapy; psoralens and ultraviolet A</td>
</tr>
<tr>
<td>96913</td>
<td>Photochemotherapy (Goeckerman and/or PUVA) for severe photoresponsive dermatoses requiring at least four to eight hours of care under direct supervision of the physician (includes application of medical dressings)</td>
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<tr>
<td>96920</td>
<td>Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm</td>
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<tr>
<td>96921</td>
<td>Laser treatment for inflammatory skin disease (psoriasis); 250 sq cm to 500 sq cm</td>
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<tr>
<td>96922</td>
<td>Laser treatment for inflammatory skin disease (psoriasis); over 500 sq cm</td>
</tr>
<tr>
<td>96999</td>
<td>Unlisted special dermatological service or procedure</td>
</tr>
</tbody>
</table>

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REFERENCES:

2. Akdis CA, Akdis M, Bieber T, et al.; European Academy of Allergy and Clinical Immunology; Clinical Immunology/American Academy of Allergy, Asthma and Immunology/PRACTALL Consensus Group. Diagnosis and treatment of atopic dermatitis in children and adults: European Academy of Allergy and Clinical Immunology/American Academy of Allergy, Asthma and Immunology/PRACTALL Consensus Report. Allergy. 2006;61(8):969-987.


patients with vitiligo. Indian J Dermatol Venereol Leprol. 2009;75(2):162-166.


81. Westerhof W, Nieuweboer-Krobotova L. Treatment of vitiligo with UV-B radiation vs topical psoralen plus UV-


POLICY HISTORY:

<table>
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<tr>
<th>DATE</th>
<th>ACTION/DESCRIPTION</th>
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<tr>
<td>02/12/2014</td>
<td>New Policy 2013M0050A. Reviewed by Interim Medical Policy Committee.</td>
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<tr>
<td>02/27/2014</td>
<td>Reviewed and approved by the Quality Improvement Advisory and Credentialing Council (QIACC).</td>
</tr>
<tr>
<td>03/01/2014</td>
<td>Published to UCare.org</td>
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