MEDICAL POLICY

Excellus

SUBJECT: LIGHT AND LASER THERAPIES FOR DERMATOLOGIC CONDITIONS	EFFECTIVE DATE: 09/21/06 REVISED DATE: 09/20/07, 07/17/08, 09/17/09, 10/28/10, 09/15/11, 09/20/12, 09/19/13, 09/18/14
POLICY NUMBER: 8.01.21 CATEGORY: Technology Assessment	PAGE: 1 OF: 9

- ***If the member's subscriber contract excludes coverage for a specific service it is not covered under that contract. In such cases, medical policy criteria are not applied.***
- ***Medical policies apply to commercial and Medicaid products only when a contract benefit for the specific service exists.***
- ***Medical policies only apply to Medicare products when a contract benefit exists and where there are no National or Local Medicare coverage decisions for the specific service.***

POLICY STATEMENT:

I. Based upon our criteria and review of peer-reviewed literature, the following have been medically proven to be effective, and therefore, are **medically appropriate:**

A. Ultraviolet B (UVB) light alone or in combination with other treatment modalities for the following indications:
1. severe psoriasis, not responsive to topical or systemic (e.g. methotrexate) drug therapies alone;
2. eczema/atopic dermatitis, not responsive to topical or systemic drug therapies alone, or that interferes with an individual's normal functional capacity;
3. cutaneous T-cell lymphoma (e.g., mycosis fungoides); or
4. vitiligo of sun exposed regions (such as the face, neck and dorsum of the hands) because the depigmented skin is sun sensitive, subject to severe sunburn and may pose a risk for skin cancer.

B. Psoralen Ultraviolet A (PUVA), for the following indications:
1. severe, disabling psoriasis, not responsive to conservative therapy or UVB therapy;
2. severe, disabling eczema/atopic dermatitis, not responsive to conservative therapy or UVA/UVB therapy;
3. cutaneous T-cell lymphoma (e.g., mycosis fungoides); or
4. vitiligo of sun exposed regions (such as the face, neck and dorsum of the hands) because the depigmented skin is sun sensitive, subject to severe sunburn and may pose a risk for skin cancer.

C. Ultraviolet A (UVA) light alone or in combination with other treatment modalities for the treatment of eczema/atopic dermatitis not responsive to topical or systemic drug therapies alone, or that interferes with an individual's normal functional capacity.

D. Targeted phototherapy using a device with FDA 510k approval (e.g., XTRAC XL™ excimer laser and VTRAC™ excimer lamp system, BClear™ lamp, and European manufactured Excilite™ and Excilite µ™ XeCL lamps) for the following:
1. treatment of moderate to severe localized psoriasis comprising less than 20% of the body area for which NB-UVB or PUVA are indicated; or
2. treatment of mild to moderate psoriasis that is unresponsive to conservative treatment

E. Home phototherapy utilizing UVB radiation for the treatment of severe psoriasis, comprising at least 10% of the body area, which is not responsive to conservative therapies or eczema/atopic dermatitis which is not responsive to conservative therapies when ALL of the following criteria have been met:
1. letter of medical necessity from the dermatologist stating the reason the home-based rather than office-based therapy is needed;
2. the patient has had ineffective courses of treatment using topical or systemic drug therapy;
3. the patient must be motivated and reliable so that treatment is pursued correctly, consistently and exposures are accurately recorded; and
4. documentation that phototherapy provided in the office was efficacious.

F. Photodynamic Therapy (PDT) with 5-ALA or Metvix® topical preparations for the treatment of:
1. non-hyperkeratotic actinic keratoses of the face and scalp;
2. superficial basal cell skin cancer only when surgery and/or radiation is contraindicated; or
3. Bowen's disease (squamous cell carcinoma in situ) only when surgery and/or radiation is contraindicated.

II. Based upon our criteria and review of peer-reviewed literature, the following have not been medically proven effective, and therefore, are considered **investigational**:
   A. Targeted phototherapy (e.g., the XTRAC XL™ and VTRAC™ lamp, the BClear™ lamp, and the European manufactured Excilite™ and Excilite µ™ XeCL lamps) for the following indications:
      1. first-line treatment of mild psoriasis; and
      2. treatment of generalized psoriasis or psoriatic arthritis; and
      3. vitiligo.
   B. PDT with topical preparations for the treatment of other dermatologic conditions including, but not limited to acne vulgaris, squamous cell carcinoma, and non-superficial basal cell carcinoma.
   C. Treatment of acne with light or laser therapy; including pulsed dye or smooth beam laser.

III. Contraindications:
   A. The following are contraindications of phototherapy and PUVA:
      1. Xeroderma pigmentosum,
      2. Disorders with significant light sensitivity (e.g., albinism), and
      3. Lupus erythematosus.

   B. The following are contraindicated for PUVA, but phototherapy may be used:
      1. Breast-feeding,
      2. Pregnancy, and
      3. Uremia and hepatic failure.

   C. Treatment should be used with *caution* in the following circumstances:
      1. History or family history of melanoma,
      2. Past history of non-melanoma skin cancer, extensive solar damage, and previous treatment with ionizing arsenic,
      3. Pemphigus or pemphigoid,
      4. Immunosuppression,
      5. Cataracts and aphakia,
      6. Photosensitivity, and
      7. Uremia and hepatic failure.

Refer to Corporate Medical Policy #7.01.11 regarding Cosmetic and Reconstructive Procedures.

Refer to Corporate Medical Policy #8.01.01 regarding Extracorporeal Photochemotherapy/Photopheresis.

Refer to Corporate Medical Policy #8.01.06 regarding Photodynamic Therapy for Malignant Disease.

Refer to Corporate Medical Policy #11.01.03 regarding Experimental or Investigational Services.

POLICY GUIDELINES:

I. The number of treatments required for clearance and remission for both UVB and PUVA therapy is based upon severity of the disease and the individual response to treatment. The number of psoriatic flare-ups a person experiences in a lifetime also varies by severity of the disease.

II. UVB therapy usually begins with 3 to 5 sessions per week until clearing is achieved followed by maintenance therapy with a gradual reduction in sessions until none are required. PUVA therapy begins with 2 to 3 sessions per week for initial clearing then 1 to 2 times a month for maintenance. If no improvement in the psoriatic lesions is seen after 4 weeks of either UVB or PUVA therapy, treatment should be discontinued.

III. Any requests for medical necessity documentation, such as a treatment plan and/or photographs, are generally not required until after a threshold of 30 visits.

IV. The number of treatments required for clearance and remission for atopic dermatitis/eczema and for repigmentation in vitiligo for both UVB a PUVA Therapy is based upon severity of the disease and the individual response to treatment.

V. In general, a phototherapy home unit should be purchased only when there is anticipation of long-term use.

VI. Because of its potential long-term side effects PUVA is rarely indicated for children or young adults.

VII. The Federal Employee Health Benefit Program (FEHBP/FEP) requires that procedures, devices or laboratory tests approved by the U.S. Food and Drug Administration (FDA) may not be considered investigational and thus these procedures, devices or laboratory tests may be assessed only on the basis of their medical necessity.

DESCRIPTION:

Ultraviolet light therapy is exposure to the skin with non-ionizing radiation for therapeutic benefit. It may involve exposure to ultraviolet B (UVB), ultraviolet A (UVA) or various combinations of UVB and UVA radiation.

Excimer laser, a xenon chloride (XeCl) laser (e.g., XTRAC, Ex-308 laser), emits 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 may shorten the number of exposures necessary, and only specific areas of the body are treated with the laser; limiting the number of exposures and the area being treated can reduce the harmful effects of UV radiation.

Photochemotherapy is the therapeutic use of radiation in combination with a photosensitizing chemical, currently Psoralens and UVA radiation (PUVA). Psoralens makes the skin more sensitive and responsive to this wavelength of light. It can be taken orally, applied topically or patients can soak in a bath of Psoralens solution.

Photodynamic therapy (PDT) using 5-aminolevulinic acid (5-ALA) has been investigated as a treatment of actinic keratoses (AK), skin cancers and superficial dermatologic lesions such as Bowen's disease. Levulan® Kerastick® is one example of a topical preparation of 5-ALA. The Levulan® Photodynamic system is a 2-step treatment, involving application of Levulan® Kerastick® then exposure of the area to blue light via the BLU-U® Blue Light Photodynamic Therapy Illuminator.

Topical application of methyl aminolevulinate (Metvix®, MAL) followed by exposure with the CureLight Broadband (Model CureLight 01), a proprietary red light source, or the PhotoCure Aktilite CL128 lamp, a LED based narrow band (630 nm) red light technology device, is another variant of photodynamic therapy for skin lesions.

The use of photodynamic therapy via the BLU-U® Blue Light Photodynamic Therapy Illuminator and intense pulsed light have been investigated for the treatment of acne vulgaris, and has received FDA approval for this indication.

Psoriasis disease severity is minimally defined by body surface area lesion characteristics (e.g., location and severity of erythema, scaling, induration, and pruritus) and impact on quality of life are also taken into account. For example, while one handprint is equal to approximately 1% body surface area, lesions on the hands, feet, or genitalia that cause disability may be classified as moderate to severe. Mild psoriasis affects less than 5% of the body's surface area, moderate psoriasis affects 5% to 10%, and severe disease affects more than 10% body surface area.

RATIONALE:

The published data has demonstrated that psoriasis has an excellent response rate when treated with either UVB or PUVA. The overall risk of complications from phototherapy and photochemotherapy are low when compared to the thousands of patients treated with these therapies. Phototherapy and photochemotherapy have been standard treatment alternatives used by dermatologists for severe psoriasis and for vitiligo.

Published data have demonstrated that phototherapy in the form of UVA, UVB and PUVA have been proven to be safe and effective treatments with a low overall risk of complications, for eczema/atopic dermatitis. The American Academy of Dermatology Association lists phototherapy and photochemotherapy as treatments for eczema in its most recently published Guidelines of Care for Phototherapy and Photochemotherapy, and Guidelines of Care for Atopic Dermatitis.

The peer-reviewed literature consists of small case series that indicate good outcomes when phototherapy in the form of PUVA and UVB is used for the treatment of mycosis fungoides, a very rare lymphoma of the skin.

PhotoMedex (XTRAC laser) and Surgilight (EX-308 laser) have received FDA 510(k) market approval for the use of excimer lasers in the treatment of psoriasis. 510(k) clearance has subsequently been obtained for a number of targeted

UVB lamps and lasers, including the XTRAC XL™ laser and VTRAC™ lamp (PhotoMedex), the BClear™ lamp (Lumenis), and the European manufactured Excilite™ and Excilite µ™ XeCL lamps. The indicated use of these devices is targeted UVB phototherapy for treatment of skin conditions including psoriasis, vitiligo, atopic dermatitis, and leukoderma. Peer-reviewed literature is limited; however, the published evidence supports the use of targeted phototherapy for the treatment of moderate to severe psoriasis comprising less than 20% body area for which NB-UVB or PUVA are indicated, and for the treatment of mild to moderate psoriasis that is unresponsive to conservative treatment. There is insufficient evidence to support the use of targeted phototherapy for the first-line treatment of mild psoriasis or for the treatment of generalized psoriasis or psoriatic arthritis. The published literature evaluating the use of targeted phototherapy to treat vitiligo consists of small case series with short-term follow-up and the data are insufficient to support its use for this indication.

The use of PDT with 5-ALA is FDA approved only for the treatment of non-hyperkeratotic actinic keratoses of the face and scalp. The use of PDT with Metvix® (US trade name Metvixia™) is FDA approved only for the treatment of non-hyperkeratotic actinic keratoses of the face and scalp in immunocompetent patients. However, off-label uses such as the treatment of basal cell carcinoma, photoaging, and acne vulgaris are common. Studies demonstrate that photodynamic therapy with 5-ALA or Metvix® is an effective nonsurgical technique of treating non-hyperkeratotic actinic keratoses (AK) of the face and scalp with an acceptable rate of recurrence over 12 months of 19% .

In 2007, the International Society for Photodynamic Therapy in Dermatology published consensus-based guidelines on the use of PDT for nonmelanoma skin cancer. Based on efficacy and cosmetic outcome, the authors recommended PDT as a first-line therapy for actinic keratosis. The guideline recommended PDT for superficial basal cell carcinoma as "a viable alternative when surgery would be inappropriate or the patient or physician wishes to maintain normal skin appearance and concludes that PDT is at least as effective as cryotherapy or 5-FU for Bowen's disease. The authors found insufficient evidence to support the routine use of topical PDT for squamous cell carcinoma. (Braathen LR, et al.)

The 2014 Clinical Practice Guidelines in Oncology from the National Comprehensive Cancer Network state that in patients with low-risk, superficial basal cell cancer or low-risk squamous cell carcinoma in situ (Bowen's disease) where surgery or radiation is contraindicated or impractical, topical therapies such as 5-fluorourcil, imiquimod, photodynamic therapy (e.g., amino levulinic acid [ALA], porfimer sodium), or vigorous cryotherapy may be considered, even though the cure rate may be lower.

A 2007 Cochrane review of Interventions for Basal Cell Carcinoma of the Skin concluded that surgery and radiotherapy appear to be the most effective treatments with surgery showing the lowest failure rates, that although cosmetic outcomes appear good with PDT long-term follow-up data are needed, and PDT appears to be useful in the short-term, especially for people who wish to avoid scarring (Bath-Hextall, et al).

Overall, the literature investigating the use of PDT in the treatment of acne consists of very small studies in which the patient serves as their own control. These studies lack long-term data on effectiveness and safety.

Due to the small sample sizes of the published trials, lack of long-term follow-up, small number of studies on any particular type of laser, and paucity of studies comparing light therapy to standard acne treatments, the evidence is insufficient to draw conclusions about the impact of laser treatments on health outcomes in patients with active acne.

CODES: Number Description

Eligibility for reimbursement is based upon the benefits set forth in the member's subscriber contract.

CODES MAY NOT BE COVERED UNDER ALL CIRCUMSTANCES. PLEASE READ THE POLICY AND GUIDELINES STATEMENTS CAREFULLY.

Codes may not be all inclusive as the AMA and CMS code updates may occur more frequently than policy updates.

CPT:	96567	Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (e.g., lip) by activation of photosensitive drug(s), each phototherapy exposure session

	96900	Actinotherapy (ultraviolet light)
	96910	Photochemotherapy; tar and ultraviolet B (Goeckerman treatment) or petrolatum and ultraviolet B
	96912	psoralens and ultraviolet A (PUVA)
	96913	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 medication and dressings)
	96920	Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm
	96921	250 sq cm to 500 sq cm
	96922	over 500 sq cm

HCPCS:	E0691	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection; treatment area two square feet or less
	E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, four foot panel
	E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, six foot panel
	E0694	Ultraviolet multidirectional light therapy system in six foot cabinet, includes bulbs/lamps, timer and eye protection
	J7308	Aminolevulinic acid HCL for topical administration, 20%, single unit dosage form (354mg)
	J7309	Methyl aminolevulinate (MAL) for topical administration, 16.8%, 1 g
ICD9:	173-173.9	Other malignant neoplasm of skin, unspecified (code range)
	199	Malignant neoplasm without specification of site
	202.1	Mycosis fungoides
	202.2	Sezary's disease
	232-232.9	Carcinoma in situ of skin (code range)
	696.0	Psoriatic arthropathy
	696.1	Other psoriasis, any type except arthropathy
	702.0	Actinic Keratosis
	706.1 **(E/I)**	Other acne
	709.01	Vitiligo
ICD10:	C44.00-C44.99	Other and unspecified malignant neoplasm of skin (code range)
	C80.0-C80.2	Malignant neoplasm without specification of site (code range)
	C84.00-C84.19	Mature T/NK-cell lymphomas (code range)
	D04.0-D04.9	Carcinoma in situ of skin (code range)

L40.0-L40.9	Psoriasis (code range)
L57.0	Actinic keratosis (code range)
L70.0-L70.9 **(E/I)**	Acne (code range)
L73.0 **(E/I)**	Acne keloid
L80	Vitiligo

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* key article

KEY WORDS:

Aminolevulinic acid, BClear lamp, Excilite lamp, Levulan® Kerastick®, methyl aminolevulinate, Metvix®, Narrow band ultraviolet B, Psoralens, PUVA, Ultraviolet light, UVA, UVB, xenon chloride laser, XeCL, XTRAC, VTRAC lamp.

CMS COVERAGE FOR MEDICARE PRODUCT MEMBERS

There is currently a National Coverage Determination (NCD) for the Treatment of Psoriasis and a NCD for the Treatment of Actinic Keratosis. Please refer to the following websites for Medicare Members:
https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=88&ncdver=1&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&KeyWord=psoriasis&KeyWordLookUp=Title&KeyWordSearchType=And&ncd_id=250.1&ncd_version=1&basket=ncd%25253A250%25252E1%25253A1%25253ATreatment+of+Psoriasis&bc=gAAAABAAAAAA&

https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=129&ncdver=1&NCAId=1&ver=23&NcaName=Actinic+Keratoses&CoverageSelection=Both&ArticleType=All&PolicyType=Final&s=New+York+-+Upstate&KeyWord=actinic+keratoses&KeyWordLookUp=Title&KeyWordLookUp=Title&KeyWordSearchType=And&KeyWordSearchType=And&ncd_id=250.1&ncd_version=1&basket=ncd%25253A250%25252E1%25253A1%25253ATreatment+of+Psoriasis&bc=gAAAABAAIAAA&