Subject: Phototherapy for Dermatitis and Eczema		Original Effective Date: 11/20/08
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PREFACE

This Medical Guidance is intended to facilitate the Utilization Management process. It expresses Molina's determination as to whether certain services or supplies are medically necessary, experimental, investigational, or cosmetic for purposes of determining appropriateness of payment. The conclusion that a particular service or supply is medically necessary does not constitute a representation or warranty that this service or supply is covered (i.e., will be paid for by Molina) for a particular member. The member's benefit plan determines coverage. Each benefit plan defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers will need to consult the member's benefit plan to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and a member's plan of benefits, the benefits plan will govern. In addition, coverage may be mandated by applicable legal requirements of a State, the Federal government or CMS for Medicare and Medicaid members. CMS's Coverage Database can be found on the following website: http://www.cms.hhs.gov/center/coverage.asp.

FDA INDICATIONS

U.S. Food and Drug Administration (FDA)[7]

The FDA has approved various light sources for the treatment of dermatologic skin conditions including atopic dermatitis (eczema) and seborrheic dermatitis. The FDA also approves phototherapy to provide ultraviolet (UVB) radiation of the body to photoactivate a drug in the treatment of dermatologic disorders.

Several devices are available for delivering phototherapy, and can be found by searching the following Product Codes in the 510(k) Premarket Notification Database: FTC (Dermatological ultraviolet light); KGL (Phototherapy PUVA cabinet); and GEX (Powered laser surgical instrument). [4 21]

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

The coverage directive(s) and criteria from an existing National Coverage Determination (NCD) or Local Coverage Determination (LCD) will supersede the contents of this Molina medical coverage guidance (MCG) document and provide the directive for all Medicare members. The directives from this MCG document may be followed if there are no available NCD or LCD documents available and outlined below.

CMS currently does not have a national coverage determination (NCD) regarding phototherapy or photochemotherapy, or light therapies for skin disorders. [5]

INITIAL COVERAGE CRITERIA

Phototherapy and Photochemotherapy may be considered medically necessary and may be authorized when ***ALL*** of the following criteria are met: [10 17 19 21 22 25 29 30 31]

- ❑ Age > 12 years

- ❑ Diagnosis of severe refractory atopic dermatitis or eczema by an allergist of dermatologist as defined by: [ALL]
  - o more than 20% skin involvement or 10% if affected areas include the eyelids, hands, or intertriginous areas; and
  - o ongoing or frequent treatment with high-potency topical glucocorticoids or systemic glucocorticoids; and
  - o severe exacerbations requiring emergency room visits, unscheduled office visits and/or hospitalizations; and
  - o ocular or infectious complications; and
  - o impairment in quality of life, such as sleepless nights, impaired activities of daily living including absence from school or work; and
  - o presence of erythrodema

- ❑ Clinical documentation of inadequate symptom control or intolerance to the following conventional treatments:

  - o First line treatments: [ALL]
    - ➢ Hydration with emollients
    - ➢ Topical corticosteroids: A second topical corticosteroid of the same potency should be considered as an alternative to stepping up treatment
    - ➢ Antihistamines
    - ➢ Antimicrobial therapy for skin infections (if applicable)

  - o Second Line Treatments: [ALL]
    - ➢ Wet dressings in combination with topical corticosteroids
    - ➢ Short-term systemic corticosteroids (if applicable)*
    - ➢ Calcineurin inhibitors** when the disease process has not shown a satisfactory clinical response to adequate use of the maximum strength and potency appropriate for the patient's age and the area being treated

**Note: The use of systemic corticosteroids is not recommended for the long-term management of a chronic atopic dermatitis because of a number of common and significant side effects. A short, tapering course of systemic corticosteroids is sometimes used to abort an acute exacerbation. However, the dramatic clinical improvement often observed is characteristically associated with an equally dramatic rebound flaring of atopic dermatitis following the discontinuation of these agents.*[19]

***Note: The FDA has issued a warning regarding a possible link between topical calcineurin inhibitors and cancer and in 2006 placed a "black box" warning on the prescribing information.*

- ❑ Phototherapy must be administered in a physician's office or setting for monitoring

CONTINUATION OF THERAPY

1. Phototherapy (UVA or UVB) may be authorized as follows:
   - ❑ Three times per week for up to 12 weeks have shown to be effective. Documentation is required after the initial 12 treatments to determine if any improvement has occurred. Treatments beyond 12 weeks require documentation for necessity. [31]

2. Psoralen with Ultraviolet A (PUVA) may be authorized as follows:
   - ❑ Three times per week for up to 15 treatments have shown to be effective. Documentation is required after 15 treatments to determine if any improvement has occurred. Treatments beyond the initial 15 require documentation for necessity. [31]

COVERAGE EXCLUSIONS

Phototherapy treatment is excluded from coverage if any of the following applies:

- ❑ ALL of the above criteria as outlined in the 'Coverage Criteria' section are not met
- ❑ Diagnosis of Seborrheic Dermatitis [20]
- ❑ PUVA or oral phototherapy treatment in children under age 12 and pregnant or breast feeding women
- ❑ Home UVA or UVB therapy as there is lack of evidence supporting safety and efficacy
- ❑ Laser therapy as there is a lack of evidence supporting safety and efficacy [25]

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Phototherapy/Actinotherapy-is used to treat various dermatological skin conditions and has been defined by the American Academy of Dermatology as "exposure to nonionizing radiation for therapeutic benefit [1]. Ultraviolet light therapy or phototherapy includes broadband UVA, broadband UVB, combined UVA and UVB, narrow-band UVB, or UVA. Phototherapy is a treatment option for moderate to severe atopic dermatitis that is not adequately controlled with topical therapy. [10]

Photochemotherapy (PUVA) involves treatment with either oral or bath psoralen followed by ultraviolet A (UVA) radiation. The treatment is an alternative to UVB and is most commonly used after UVB treatment proves to be ineffective. PUVA is known to have antiproliferative, anti-inflammatory and immunosuppressive effects. Treatment with these modalities may involve partial or whole-body exposure.[1] Photochemotherapy includes psoralens (P) and Ultraviolet A (UVA) radiation, known as PUVA photochemotherapy.

Atopic Dermatitis (eczema) - A common skin condition atopic dermatitis is associated with pruritus.[4] Scratching often leads to redness, swelling, cracking, and oozing of clear fluid, crusting, and scaling of the skin. Intensely itchy patches form, which can be widespread or limited to a few areas. Between 10 and 20 percent of people worldwide develop atopic dermatitis, making it the most common type of eczema. For an estimated 65 percent, atopic dermatitis begins during their first year of life, and 90 percent have the condition before age 5. While rare, atopic dermatitis can first appear at puberty or later. IgE antibodies may be elevated in up to 80% of individuals with atopic dermatitis, the skin manifestations do not seem to be a purely IgE-mediated process. The etiology of atopic dermatitis is unknown. One theory involves the possibility that an aberrant T cell response, to staphylococcal superantigen, results in the activation of TH2 cells. After approximately two years of age, most individuals will present with a more chronic, lichenified and scaling form of the disease distributed about the

face, neck, trunk and especially the flexural aspects of the extremities (antecubital and popliteal fossae). Individuals with atopic dermatitis are prone to develop secondary infection with staphylococcal organisms, as well as with viruses and fungi.[4]

Seborrheic Dermatitis- Seborrheic dermatitis is a common skin disorder that can be easily treated.[5] Causing a red, scaly, itchy rash, this condition most commonly develops on the scalp, sides of the nose, eyebrows, ears, eyelids, and middle of the chest. Other areas, such as the navel (belly button), buttocks, underarms, breasts, and groin, may be involved. Seborrheic dermatitis most often occurs in babies younger than 3 months of age and in adults from 30 to 60 years of age. In adults, it's more common in men than in women. The exact cause is not known. The cause may be different in infants and adults. Seborrheic dermatitis is thought to be related to hormones as the disorder often appears in infancy and disappears before puberty. A fungus called malassezia is normally present on the skin in small numbers, but when its numbers increase skin problems occur. Seborrheic dermatitis has also been linked to neurological disorders such as Parkinson's disease and epilepsy. The reason for this relationship isn't known.[5]

GENERAL INFORMATION

Summary of Medical Evidence

The evidence in the published peer-reviewed scientific literature in the form of systematic reviews, randomized controlled trials, case series, and retrospective reviews 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. [6 9 12 13 23 26 27 28]

There are a limited number of studies evaluating laser therapy for the treatment of atopic dermatitis. A small randomized controlled trial (n=10) was conducted 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. 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. Limitations of the study included the small patient population, selection of more severely affected patients, loss of blinding due to sustained hyperpigmentation in the laser group and the use of various radiant exposures.[24]

Systematic Reviews for Atopic Dermatitis (AD)

A recent (2014) was conducted to evaluate the effect of treatment with photo (chemo) therapy in patients with AD and to make treatment recommendations on basis of the evidence. Nineteen studies were included (905 participants). Ultraviolet (UV) A1 and narrowband (NB)-UVB appeared the most effective treatment modalities for the reduction of clinical signs and symptoms. No difference between high-dose UVA1 and medium-dose UVA1 was seen. UVAB was shown to be more effective than UVA and broadband-UVB for the improvement of clinical symptoms, but not compared with UVA1. Other effective treatment options include

full-spectrum light, psoralen plus UVA and balneophototherapy. No serious side-effects were reported. The reviewers concluded that phototherapy can be a valid therapeutic option for patients with AD. Based on the results of this review, preference is given to UVA1 and NB-UVB. Further well-designed, adequately powered RCTs are required. [28]

Another systematic review (2007) was conducted to evaluate the effectiveness of phototherapy in the management of atopic dermatitis.[6] Nine controlled clinical studies met the inclusion criteria. Five clinical studies evaluated the treatment of severe acute atopic dermatitis. Four studies evaluated treatments for chronic AD. Three of the studies for severe, acute AD evaluated the optimal wavelength for treatment and two investigated dosing regimens for treatment with UVA1. The four studies reviewing chronic AD were designed to determine optimal treatment wavelength.

A Health Technology Assessment and systematic review was performed to evaluate treatments for atopic eczema.[7] The authors concluded "there was reasonable evidence to support the use of ultraviolet light therapy." Ultraviolet light therapy is recommended as a second line treatment after failure of pharmaceutical agents. There is some RCT evidence to support the use of UVB (broad and narrow band) versus placebo in atopic eczema. The recommendation is based upon Randomized-control trial (RCT) data supporting the use of high dose UVA in preference to UVB/UVA. RCT data supports the use of narrow band UVB (TLO1) in preference to ordinary UVA in atopic eczema. There is RCT data that supports high dose UVA for eczema flares having slightly superior efficacy compared with topical steroids.[7]

Data was analyzed in 230 patients treated with low, medium, and high dose UVA1 therapy during a six year period.[8] The mean single dose, mean number of irradiations and the mean total dose were evaluated. Eight-six patients with atopic eczema (39 males, 47 females, age 40.22 $\pm$ 16.6 years) by a grading scale: (-2) withdrawal after six irradiations; (-1) aggravation; (0) no change; (1) slight improvement; (2) moderate improvement; (3) marked improvement; (4) complete healing. Positive results were identified in 84.8% of the patients: 11.6% scored 1, 26.7% scored 2, 43.1% scored 3, 3.5% scored a 4.

In total, 50 children (83%) completed more than 10 exposures of NB-UVB.[10] Complete clearance or minimal residual activity was achieved in 20 children (40%). Good improvement was achieved in 10 children (23%), and a moderate improvement in 13 (26%). A statistically significant improvement was noted in children with minimal erythema dose (MED) > 390 mJ/cm^2 were more likely to clear, and this was found to be statistically significant (P = 0.02). Overall, the treatment was well tolerated and the median length of remission was 3 months. NB-UVB is an effective treatment for children with severe AD. Children with MEDs > 390 mJ/cm^2 are more likely to clear. The authors concluded that further studies are needed to evaluate the efficacy of NB-UVB and long-term safety in treating children with severe AD.[9]

Several other recent studies provide evidence to support the use of UVB, nbUVB, PUVA, UVA and combination treatments as safe, effective and well tolerated therapies for the treatment of atopic dermatitis.[11-14]

Seborrheic Dermatitis

Seborrheic Dermatitis has not been well studied using phototherapy.[20] Generally, topical treatments and avoidance of irritants is recommended. Weston provided evidence review on treatment processes for seborrheic dermatitis. Phototherapy was not one of the recommended treatment options.[20]

Adverse effects associated with Phototherapy and the Development of Skin Cancer

A three center evaluation of adverse events experienced by 8784 patients treated with NbUVB (68%), bath PUVA (19%), hand/foot PUVA (10%) systemic PUVA (3%) was conducted. A total of 70 events were reported. Systemic and bath PUVA experienced the highest percent of events at 1.3% each, NbUVB (0.6%), hand/foot PUVA 0.8%. Noncompliance of the patient resulted in mild to moderate erythema in fifteen patients. Operator error attributed to two events. One patient experienced nausea and vomiting with PUVA and three episodes of sever erythema with blistering was documented with nbUVB. [20]

Hayes, Cochrane, UpToDate

There are two Hayes Health Technology Brief reports on the topic of Office-Based Phototherapy for Treatment of Atopic Dermatitis in Adults and in Children. These reports indicate that for adults, despite the lack of solid evidence, phototherapy is a reasonable treatment option in adults with intractable symptoms whose AD is refractory to standard medical therapies, and who are able to comply with instructions and adhere to the treatment schedule. In children long-term data are lacking, additional well-designed trials with sufficient numbers of patients are necessary to more definitively establish the safety and optimal role of phototherapy children with AD. [21 22]

UpToDate has topics on the management of severe refractory atopic dermatitis (eczema) and the treatment of atopic dermatitis (eczema). These reports indicate that Ultraviolet (UV) light therapy is a second-line treatment for severe atopic dermatitis in adolescents and adults. Options for phototherapy include narrowband UVB, UVA1, psoralens plus UVA (PUVA), broadband UVA, broadband UVB, and combined broadband UVA and UVB. The administration of phototherapy requires the availability of equipment and trained personnel. Potential short-term side effects (itch and acute burns) and long-term risks (premature skin aging and increased risk of skin cancer) may occur with phototherapy. [10 19 29 30]

Professional Organizations

The American Academy of Dermatology (2004, archived 2009) has established guidelines of care for atopic dermatitis by a dermatology work-group. The group indicated "ultraviolet (UV) phototherapy, including combination broad-band UVB/UVA, narrow band UVB therapy, chemo phototherapy using methoxypsoralen (PUVA) and UVA1 (wavelength 340 to 400nm) is well established in the treatment of atopic dermatitis, although relapse following cessation of therapy frequently occurs. Topical corticosteroids are the standard of care to which other treatments are compared." [14]

The National Institute for Health and Clinical Excellence (2007) developed guidelines for atopic eczema in children. The guideline addresses children from birth to 12 years. The guideline indicates phototherapy should only be considered for "severe atopic eczema when other management options have failed or are inappropriate or there is significant impact on the quality of life. Treatment should be undertaken only under specialist dermatological supervision by staff that are experienced dealing with children". [16]

A Joint Task Force on Practice Parameters delegated by the *American College of Allergy, Asthma, and Immunology, the Joint Council of Allergy, Asthma and Immunology and the American Academy of Allergy, Asthma, and Immunology* to develop guidelines for atopic dermatitis (2004 and updated 2012). First line treatments are recommended as emollients, topical corticosteroids, topical calcineurin inhibitors, and antihistamines. Treatment for difficult to manage patients include wet dressings and occlusion, systemic glucocorticosteroids and phototherapy. The authors indicate that UV therapy can be a useful treatment for recalcitrant AD. The most effective phototherapy option that is available in the United States is narrowband UVB. The clinician should consider referral to a center with phototherapy availability. [17] [31]

The American Academy of Family Physicians (2007) has developed treatment options for atopic dermatitis.[28] The first line recommendations include emollients with or without moisturizers, topical corticosteroids, antihistamines, and antibiotics for infected lesions. The authors indicate "topical corticosteroids are safe and effective for the treatment of atopic dermatitis flare-ups when used for up to four weeks, although many flare-ups may be adequately controlled with a shorter treatment course."[18] Topical calcineurin inhibitors are recommended as a second line treatment option. The authors also indicate "ultraviolet (UV) phototherapy using UVB, narrow-band UVB, UVA, or psoralen plus UVA may be beneficial for the treatment of severe disease if it is used appropriately, depending on the patient's age."[18]

The National Institute for Arthritis and Musculoskeletal and Skin Diseases identifies UVA, UVB, or a combination of both as an effective treatment modality "for mild to moderate dermatitis in older children (e.g., over 12 years) and adults. PUVA is also recommended as a potential treatment option.[15]

CODING INFORMATION: THE 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. COVERAGE IS DETERMINED BY THE BENEFIT DOCUMENT. THIS LIST OF CODES MAY NOT BE ALL INCLUSIVE.

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

HCPCS	Description
E0691	Ultraviolet light therapy system panel, includes bulbs/lamps, timer, and eye protection; treatment area 2 sq. ft. or less
E0692	Ultraviolet light therapy system panel, includes bulbs/lamps, timer, and eye protection, 4 ft. panel
E0693	Ultraviolet light therapy system panel, includes bulbs/lamps, timer, and eye protection, 6 ft. panel
E0694	Ultraviolet multidirectional light therapy system in 6 ft. cabinet, includes bulbs/lamps, timer, and eye protection

ICD-9	Description
691.8	Other atopic dermatitis and related conditions

ICD-10	Description
L20.89	Other atopic dermatitis
L20.9	Atopic dermatitis unspecified
L30.8	Other specified dermatitis
L30.9	Dermatitis unspecified
The following Diagnoses are Not Covered:	
L20.83	Infantile acute chronic eczema
L21.0	Seborrhea captitis
L21.1	Seborrheic infantile dermatitis

L21.8	Other seborrheic dermatitis
L21.9	Seborrheic dermatitis unspecified

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10/26/11 – New evidence review was conducted by the MCG Committee. The document was approved without revision.

4/2014 Update

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