

Subject: Phototherapy (Ultraviolet Light and PUVA) and Targeted Phototherapy (308-nm maximum radiation laser) for Psoriasis		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)¹¹

Phototherapy and photochemotherapy light sources for the treatment of psoriasis are approved by the FDA as Class II, 510(k) phototherapy units. These are approved for various skin conditions. Lasers are regulated by the FDA as Class II devices and are also approved for various skin conditions. A class II device is those which general controls alone are insufficient to assure safety and effectiveness. A Class II designation is subject to special control requirements. Certain laser surgical equipment used for dermatology and general or plastic surgery are not exempt from the 510(k) process. To receive 510(k) approval, the device must be considered equivalent to a device already available on the US market. Manufactures are then not required to supply the FDA evidence of effectiveness of the device by providing clinical trial data prior to marketing the device.

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 has an NCD for the Treatment of Psoriasis (250.1)¹⁰ that indicate the following treatments are covered:

- Topical application of steroids or other drugs; ultraviolet light (actinotherapy); and coal tar alone or in combination with ultraviolet B light (Goeckerman treatment).
- PUVA therapy is covered for treatment of intractable, disabling psoriasis, but only after the psoriasis has not responded to more conventional treatment. In addition, reimbursement for PUVA therapy should be limited to

amounts paid for other types of photochemotherapy; ordinarily, payment should not be allowed for more than 30 days of treatment, unless improvement is documented.

CMS has several LCDs for Laser Treatment of Psoriasis⁸² that indicate that the use of the 308-nm excimer is covered for the treatment of psoriasis in patients who have all of the following:

- mild to moderate plaque type psoriasis, defined as 10% or less of the total body surface area affected;
- psoriasis plaques have been present and unchanged for a minimum of two months,;
- total surface area to be treated is 10% or less of the total body surface; and
- the laser treatment device must meet Food and Drug Administration (FDA) approval for the treatment of psoriasis.

A single course of treatment is limited to 10 sessions per target area generally performed over the span of three to four weeks. The treatment target area will be no more than 10% of the total body surface area. Due to the nature of this condition, treatment may involve one single site, or encompass several sites that collectively equal 10% or less.

INITIAL COVERAGE CRITERIA

1. Phototherapy (UVA or UVB) with or without topical preparations (e.g., calcipotriol (Dovonex), tacalcitol, Tazaretene (Tazorec) 0.1% gel, tar also known as Goeckerman therapy) may be authorized when **ALL** of the following criteria are met:^{8 83}

- Documentation supporting a diagnosis of moderate-to-severe psoriasis (approximately 10 % to 20% body surface area) and extensive large plaque psoriasis or involvement of the face, palm or sole, or disease that is otherwise disabling; photograph of the affected area is appropriate for review; and
- Prescribing physician is a dermatologist or rheumatologist; and
- Documentation to show that good symptom control could not be achieved despite using at least 3 different topical treatments options (unless side effects limit a treatment trial with a particular agent) during a six month period (e.g., corticosteroids, Tazorac, Doconox, anthralin, salicylic acids tars); or
 - Documentation of absolute or relative contraindications to topical corticosteroids and/or other topical agents based on current medical literature; or
 - Documentation of intolerance due to clinical side effects; or
 - Documentation of substantial body surface area too large to be treated by topical treatments such as greater than 50% body surface area

2. Psoralen with Ultraviolet A (PUVA) may be authorized when all of the following criteria are met:^{8 74 83 90}

- Documentation supporting a diagnosis of severe recalcitrant psoriasis (approximately 10 % or more body surface area) or extensive large plaque psoriasis or involvement of the face, palm or sole, or disease that is otherwise disabling/ or severe; photograph of the affected area is appropriate; and
- Prescribing physician is a dermatologist or rheumatologist; and
- Documentation to show that good symptom control could not be achieved despite using at least 3 different topical treatments options (unless side effects limit a treatment trial with a particular agent) during a six month period (e.g., corticosteroids, Tazorac, Doconox, anthralin, salicylic acids tars); or
 - Documentation of absolute or relative contraindications to topical corticosteroids and/or other topical agents based on current medical literature; or

- Documentation of intolerance due to clinical side effects; and
- Documentation supporting inadequate symptom control/improvement following a three month trial of ultraviolet light (UVB) therapy

NOTE: Home UV phototherapy (Ultraviolet light only) may be authorized only for those patients that have difficulty in maintaining frequent office visits due to their medical condition or considerable distance in travel from home to office (e.g. >45 minutes one way). A 2-3 month course of outpatient UV light therapy, followed by a 2-3 month trial of reduced or discontinued UV phototherapy must first be conducted with chart note documentation substantiating improvement in condition and patient safety.⁹⁹ Home UV phototherapy is considered NOT medically necessary for patients who need courses of outpatient UV phototherapy every 6 months, but with 3-6 months of clearance in between.⁹⁹

3. Targeted Excimer Laser therapy, pulsed dye laser (PDL), and ultraviolet 1 (UVA1) laser therapy are considered investigational and unproven for the treatment of psoriasis due to insufficient evidence in the peer reviewed literature and may NOT be authorized.⁹⁸

Reference MCG-026 for Psoriasis Biological Therapies

CONTINUATION OF THERAPY

1. Phototherapy (UVA or UVB) with or without topical preparations (e.g., calcipotriol (Dovonex), tacalcitol, Tazaretene (Tazorec) 0.1% gel, tar also known as Goeckerman therapy) may be authorized as follows:^{8 12 83}
 - **Initial Treatment:** Three times weekly for 18 to 25 treatments have shown to be effective. Documentation is required after 12 treatments to determine if any improvement has occurred. Treatments beyond 25 require documentation for necessity.^{12 83 93}
 - **Maintenance:** When 95% psoriasis clearing is achieved, 1 treatment weekly for at least 2 treatments; followed by 1 treatment every 2 weeks for at least 2 treatments; then every three weeks for at least 2 treatments continue as needed to maintain response while minimizing UVA exposure.⁸³

2. Psoralen with Ultraviolet A (PUVA) may be authorized as follows:^{8 81 90 93}
 - Three times weekly until remission, then once or twice weekly as maintenance. Documentation is required after 12 treatments to determine if any improvement has occurred. Treatments beyond 25 initially, require documentation for necessity.

COVERAGE EXCLUSIONS

1. The following phototherapy treatment options are considered investigational and excluded from coverage:
 - All requests for treatment that do not meet the coverage criteria above
 - The use of home phototherapy for PUVA as there is lack of evidence supporting its safety
 - Targeted phototherapy for mild, moderate or generalized psoriasis due to lack of large randomized trials with long term follow-up.
 - Targeted phototherapy has not been proven in pregnancy, children, or breast feeding women
 - Targeted Excimer laser, Pulsed dye laser (PDL), and ultraviolet 1 (UVA1) laser therapy⁹⁸

2. Contraindications to PUVA therapy include:^{77 78 81}

- Pregnant and breast feeding women
- Children < 12 years of age

3. Contraindications for PUVA and UV light include: ^{77 81 96}

- Lupus erythematosus
- Xeroderma pigmentosum
- Albinism
- Porphyria
- Cataracts
- Aphakia
- Severe, heart, kidney, or liver disease
- Suppressed immune system (i.e. radiation therapy, burns, chemotherapy)
- Melanoma or invasive cutaneous squamous cell carcinoma
- Skin sensitivity disorder

DESCRIPTION OF PROCEDURE/SERVICE/PHARMACEUTICAL

Phototherapy-(Ultraviolet Light broadband and narrowband/Photochemotherapy)

UVB is defined as exposure to nonionizing radiation for therapeutic benefit.¹ Various types are included in this definition including ultraviolet light (broadband-BUVB and narrowband-NUVB) and photochemotherapy (psoralen plus ultraviolet A radiation). UVB phototherapy has multiple mechanisms including inhibiting DNA synthesis and epidermal keratinocyte hyperproliferation, inducing T-cell apoptosis, and inducing immunosuppressive and anti-inflammatory cytokines.⁴³ Each of these is attributed to antipsoriatic activity. 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.⁸ PUVA is known to have antiproliferative, anti-inflammatory and immunosuppressive effects. PUVA has higher success rates but also increased side effects.

Targeted excimer laser emits light beam at wavelength of 308nm compared to 311-313 with ultraviolet light (narrowband or broadband).⁶² The light is transmitted through a hand-held articulated arm held approximately 0.5-1cm away from the lesion. A diameter of 14 to 30nm is targeted to a small area of the skin. Thus, only patients suffering from small areas are a candidate for the excimer laser. Targeted excimer laser uses a higher fluency than NUVB to target psoriatic plaques selectively, resulting in fewer required treatments and a lower dosage accumulation.⁶³

Psoriasis is a chronic inflammatory multisystem disease, predominantly affecting skin and/or joints that is classically characterized by thickened, red areas of skin covered with silvery scales.² Plaque psoriasis is the most common type of psoriasis. These patches, or plaques, frequently form on the elbows, knees, lower back, and scalp but can occur anywhere on the body. The other types are guttate psoriasis often found in young patients following streptococcal throat infections, pustular psoriasis mainly affecting the palms and soles, inverse psoriasis (smooth, red lesions form in skin folds), and erythrodermic psoriasis or generalized psoriasis which may cause systemic upset (e.g., fever, dehydration and raised white blood cell count).^{73 93}

Classifications of Disease Severity

Several classification systems based on disease severity have been created to guide treatment decisions in psoriasis. Some of these classifications include the Psoriasis Area Severity Index (PASI) and the Physician Global Assessment (PGA) both considered the most commonly used tools to assess psoriasis activity and clinical response to treatment.¹⁷ The National Psoriasis Foundation (NPF) has also developed the NPF Psoriasis Score (NPF-PS). The PASI evaluates the degree of erythema, thickness scaling of psoriatic plaques, and estimates the extent of involvement of each of these components into four separate body areas (head, trunk, upper and lower extremities).¹⁷ The PASI is scored on a point system from 0 to 72, with higher numbers being more severe. A PASI score of > 10 (range 0-72) has been shown to correlate with a number of indicators commonly associated with severe disease such as need for hospital admission or use of systemic therapy.¹⁹ The Dermatology Life Quality Index (DLQI) is another validated tool for the measurement of quality of life across all skin diseases in both trial and clinical practice settings and a score of > 10 (range 0-30) has been shown to correlate with at least 'a very large effect' on an individual's quality of life.¹⁹ According to Feldman et al., "moderate-to-severe psoriasis is typically defined as involvement of more than 5 to 10 percent of the body surface area (the palm of one hand is approximately 1 percent of the body surface area) or involvement of the face, palm or sole, or disease that is otherwise disabling. Patients with more than 10 percent body surface area affected are generally candidates for systemic therapy, since application of topical agents to a large area is not usually practical or acceptable for most patients."^{8,9}

Classification

- Mild Psoriasis: Less than 5% of body surface area (BSA)
- Moderate Psoriasis: 5% to 10% of BSA
- Severe Psoriasis: > 10% of BSA

Treatment Options

Topical therapy is the initial treatment for psoriasis. Emollients, keratolytics, salicytic acid, coal tar, anthralin, calcipotriene, corticosteroids, tazarotene are the recommended first line treatments.⁷³ Phototherapy is indicated for moderate-to-severe psoriasis and extensive large plaque psoriasis and should be referred to an appropriate specialist center. NUVB has been proven most effective when given three times weekly for approximately 6 weeks. Recent care guidelines indicate 20 to 25 treatments may be required for significant improvement.¹² PUVA with oral or topical psoralen (usually 8-methoxsalen) is suitable for extensive large plaque psoriasis. PUVA is administered two to three times weekly and is effective for generalized disease.⁷⁴ The treatment regimen is divided into two phases: the clearance phase, in which continual treatment is given until clearing occurs, followed by the maintenance phase, in which treatments are given less frequently but in numbers sufficient to prevent a flare-up of the disease.⁷⁵

GENERAL INFORMATION

Summary of Medical Evidence

Systematic Review

A systematic review and meta-analysis by Almutalwa et al. (2013) was conducted to evaluate the efficacy, short-term safety, and tolerability of UV-based therapy in the treatment of adults with moderate to severe plaque psoriasis. Randomized controlled trials (RCTs) evaluating NB-UVB, BB-UVB, and PUVA in adults with moderate to severe plaque-type psoriasis were reviewed. Forty-one RCTs, with a total of 2,416 patients, met the eligibility criteria and were included in the analysis. In regard to PASI-75 in monotherapy trials, PUVA (mean: 73 %, 95 % CI 56-88) was the most

effective modality. Trials with BB-UVB also showed a high PASI-75 (73 %) but with a wide CI (18-98) due to heterogeneity of the total available three studies. This was followed by NB-UVB (mean: 62 %, 95 % CI 45-79) then bath PUVA (mean: 47 %, 95 % CI 30-65). In regard to clearance in the monotherapy trials, PUVA (mean: 79 %, 95 % CI 69-88) was superior to NB-UVB (mean: 68 %, 95 % CI 57-78), BB-UVB (mean: 59 %, 95 % CI 44-72), and bath PUVA (mean: 58 %, 95 % CI 44-72). The percentages of asymptomatic erythema development in monotherapy trials were 64 % for BB-UVB, 57 % for NB-UVB, 45 % for PUVA, and 34 % for bath PUVA. Symptomatic erythema or blistering percentages for the monotherapy trials were as follows: 7.8 % for NB-UVB, 2 % for BB-UVB, 17 % for PUVA, and 21 % for bath PUVA. The percentages of withdrawal due to adverse effects were 2 % for NB-UVB, 4.6 % for BB-UVB, 5 % for PUVA, and 0.7 % for bath PUVA monotherapy trials. The authors concluded that as a monotherapy, PUVA was more effective than NB-UVB, and NB-UVB was more effective than BB-UVB and bath PUVA in the treatment of adults with moderate to severe plaque-type psoriasis, based on clearance as an end point. Based on PASI-75, the results were similar except for BB-UVB, which showed a high mean PASI-75 (73 %) that was similar to PUVA, but with a wide CI (18-98). The short-term adverse effects were mild as shown by the low rate of withdrawal due to adverse effects.⁹⁵

UVB Monotherapy

The efficacy of NB-UVB has been demonstrated in clinical trials. Approximately 63-80% of all patients achieve clearance after approximately 15-20 treatments are required to achieve 50% improvement.^{46,47} More recent randomized control trials published in peer-reviewed literature report improvements in symptoms and severity index scores following therapy. One study indicated that 92% of patients achieved PASI score of 7 following 12 weeks of UVB treatment²¹. The group that continued with UVB maintenance had 55% patients in remission versus 33% without maintenance. Plaque psoriasis had a better outcome than guttate-type psoriasis (57% versus 17%).²¹ Targeted UVB produced significant improvement in PASI scores in 77% of patients for up to 4 weeks using 3 doses weekly.²² One study showed no statistical difference in broadband (40%) versus narrowband patients (56%) achieving clearance.²⁰ Three radiation treatments of UVB a week have shown to be more effective than 2 or 5 treatments.^{25,42}

The primary adverse effect of UVB reported in 10 to 90 percent of patients is erythema.^{46,47} Other short-term adverse effects reported with the use of UVB include blistering of plaques, dry skin with pruritus (may be related to the underlying disease) and increased frequency of herpes simplex reactivation.^{46,48} Long term adverse effects reported include photodamage and a possible dose related incidence of skin cancer.^{46,48,49} Skin cancer has not been precisely quantified ; however, one systematic review stimulated the excess annual risk of nonmelanoma skin cancer associated with UVB use is less than 2%.⁵⁰ According to Naldi and Griffiths “due to the risk of carcinogenesis, NB-UVB should be reserved for patients with moderately severe disease who cannot tolerate or do not respond to topical treatments. NB-UVB is contraindicated in patients with xeroderma pigmentosum or systemic lupus erythematosus, and should be avoided in patients with a history of skin cancer. Current guidelines recommend careful monitoring of patients considered to be at risk of skin cancer, and particular caution for patients with skin typed I-II, and blonde or red hair.”⁴³

UVB and Topical Combination Therapies

Several randomized control studies have shown successful results with UVB in combination with other treatments. UVB with vitamin D3 analogues including calcipotriol (Dovonex) and tacalcitol has been evaluated in several studies and are considered safe and efficacious.²⁵⁻²⁸ Plaque clearance has been noted to clear faster with vitamin D application.²⁹⁻³¹ Tazarene (Tazorec) 0.1% gel combined with nUVB produced faster and significantly greater reduction in psoriasis

plaques with significantly lower median cumulative UV exposure than UVB alone.^{32,33} Tar treatments used with ultraviolet radiation including Goeckerman regimen have been effective in clearing mild psoriasis.⁷⁶ The addition of calcipotriol ointment in targeted phototherapy enhances the therapeutic effects of phototherapy in the treatment of plaque-type psoriasis.⁹³ Combination treatments consisting of vitamin D derivative and corticosteroid, vitamin D derivative and UV-B, vitamin A derivative and psoralen-UV-A, vitamin A derivative and corticosteroid, vitamin A derivative and UV-B, corticosteroid and hydrocolloid occlusion dressings, UV-B and alefacept, and vitamins A and D derivatives were more effective than 1 or more monotherapies using the likelihood of clearance as the outcome.⁹⁴

A systematic review of evidence-based recommendations on topical treatment and phototherapy of psoriasis was conducted by Gallini and associates (2012). A total of 3555 references were identified, among which 312 articles were included in the systematic reviews. Three recommendations were issued on phototherapy including both PUVA and narrow-band UVB. The recommendations related to administration schedule, clearance rate and risk of side-effects. The mean agreement between participants was good varying from 8.5 to 9.5. Six recommendations were issued on topical treatments focusing on administration schedule, clearance rate, risk of side-effects, cost-effectiveness and measures to improve treatment adherence. These recommendations for the use of topical agents and phototherapy in psoriasis are evidence-based and supported by a panel of dermatologists.⁹¹

UVB and Systemic Combination Therapy

UVB with acitretin has shown to improve the efficacy of nUVB nearly reaching the effectiveness of PUVA.³⁴ One study evaluated plaque psoriasis patients refractory to treatment.³⁵ Low dose acitretin (25mg po daily) with narrowband UVB three times weekly resulted in 75% improvement in 72.5% of 40 patients. Only 5 patients had less than 50% improvement. A second study revealed similar results.³⁶ Retinoids have also been associated with protecting against development of squamous cell cancer.³⁷⁻⁴⁰ Combination therapy of nUVB with systemic retinoids is considered an alternative to refractory treatments to avoid large cumulative doses of PUVA.⁴¹ The addition of nbUVB to treatment with alefacept significantly enhanced and accelerated the clinical benefits of alefacept therapy and was generally safe and well-tolerated.⁹²

Photochemotherapy (PUVA)

One double-blind randomized study (n=93) compared oral psoralen (PUVA) therapy to narrowband UVB in patients with chronic plaque psoriasis. The results indicated “patients with skin types V and VI had a lower rate of clearance than those with skin Types I through IV (24% vs. 75%; p=.001). PUVA was significantly more effective than nb-UVB at achieving clearance (84% vs. 65%; p=.02). The median number of treatments to clearance was significantly lower in the PUVA group. PUVA therapy with oral methoxsalen was found to be highly effective (17 vs 28.5; p<.001). Sixty-eight percent of PUVA treated patients were still in remission vs. 35% of nb-uvb treated patients.”¹⁶ This study was the first to compare UVB and PUVA. Previous clinical trials have suggested PUVA is effective for most forms of psoriasis and produces partial or complete remission in 70-90% of patients with psoriasis.^{44,45} PUVA with oral methoxsalen 0.6 to 1.0 mg/kg was found to be highly effective in clearing psoriasis.¹⁵ The treatment sequence is recommended three times weekly in increasing doses until remission, then once or twice weekly as a maintenance dose.⁸

Combination retinoid plus UVA and concomitant use of topical treatments with PUVA increased the efficacy in clearing psoriasis plaques than when given alone.¹⁵ Scientific research has shown PUVA combined with methotrexate therapy can be highly effective but the risk of excessive immunosuppression and additive carcinogenesis is a factor that limits this treatment.^{44,51,53,54}

Short term adverse events associated with the use of PUVA include pruritus, nausea and delayed sunburn-like erythema.^{44,54} Acute ocular events (e.g., conjunctival hyperaemia and decreased lacrimation) have been noted in patients that do not wear adequate eye-protection during treatment.⁵⁵ Long-term effects associated with PUVA are photodamage and premature aging of the skin with an increased incidence of irregular pigmentation, lentiginosities and actinic keratoses.^{44,54} PUVA has been associated with an increased risk of nonmelanoma skin cancer.⁵⁶⁻⁵⁹ Four melanomas occurred within the 15 years following treatment and seven occurred in the next five years. The risk increased with patients receiving more than 250 treatments. One study reported nine patients with 11 melanomas from a cohort of 1380 patients diagnosed with psoriasis and receiving PUVA treatment. An increased risk of genital cutaneous tumors mainly squamous cell carcinomas in men even if genital protection had been used.⁶⁰

A large, open randomized trial reported treatment with UVB after saltwater bath was more efficacious than UVB following tap-water bath and similar efficacy to bath PUVA.⁵² Treatment assignment was known to approximately 60 percent of the cases even though the intention was to be blinded. Less than 50 percent of patients enrolled met the prespecified criteria. No difference was found between saltwater and tap-water baths, and bath PUVA was superior to UVB after a saltwater bath. Additional studies are needed to determine if combining saltwater baths with phototherapy is superior to tap-water bath combined with phototherapy or with phototherapy alone.

Targeted Laser (308nm-excimer)

A small body of primarily low-quality evidence demonstrates a beneficial effect of treatment with excimer laser and pulsed dye laser (PDL) therapy for patients with plaque psoriasis. However, outstanding questions remain regarding the type of laser therapy that is most effective, the comparative effectiveness versus standard therapy, patient selection, long-term effectiveness and safety, as well as optimal treatment/testing parameters.⁹⁸

Large randomized controlled trials with long-term follow-up have not been conducted on 308-nm excimer laser. The longest follow-up compared with other studies was 1 year, and 13 of the 26 patients followed had persistent clearance. An improvement of >50% was seen in 90% of patients receiving 6-10 treatments.⁶⁹ There have been many small studies consistently showing targeted laser as a safe and effective treatment using a higher fluency than other phototherapy options resulting in fewer required treatments and a lower dosage accumulation. Improvement has not been noted to be consistently superior to other conventional phototherapy treatment modalities but it has been shown to be as effective as other phototherapy modalities. Gattu et al indicates “long-term follow-up of large numbers of patients receiving excimer laser therapy is needed to assess risk for skin cancer...Larger, well-controlled studies are needed with long-term follow-up to assess remission and long term risks.”⁶²

A review of the medical literature (2008) was conducted to evaluate the efficacy of excimer 308nm laser and its most recent trials associated with psoriasis.⁶² Eighteen clinical trials were included in the review. The author concludes “eighteen trials show positive results surrounding the efficacy of the excimer. Selectivity of the 308-nm excimer, when compared with non-selective narrowband UVB (NB-UVB) phototherapy allows one to adjust the fluency to the lesion. The excimer may also stand superior to NB-UVB in its efficacy. Excimer is a useful and effective treatment for psoriasis that may be used as a complement to topical medications as well as NB-UVB. However, large randomized trials with long-term follow-up are needed to further support this.”⁶²

Two small blinded controlled studies compared targeted UVB with standard phototherapy of psoriasis; both using equivalent doses and patches on either side of the body showed similar results in improvement.^{64,65} One study with 10

patients compared cream PUVA with 308 nm UVB with palmoplantar psoriasis both groups had similar reduction in PASI score 208-nm 63.57% versus in PUVA cream 64.64% after 20 treatments.⁶⁴ The second blinded study compared 16 patients with psoriasis vulgaris following 20 treatments showed similar improvement in PASI scores on both sides (11.8 to 6.3 for laser and 11.8 to 6.9 for nontargeted NBUVB).⁶⁵ The authors reported that this method is difficult to use in widespread generalized disease as the laser has a 2 x 2 cm surface area size making it difficult to treat large body areas. Similar results were noted evaluating the laser with narrowband ultraviolet b.⁶⁵ UVB is known to treat larger body areas that are difficult to treat with other modalities such as topical therapy. Excimer laser is only recommended for areas that involve 10% or less of body surface area and those patients that have failed conventional treatment methods.

A multicenter open trial of 124 patients with mild to moderate psoriasis reported effective clearance among the 80 patients that completed XeCL laser treatment.⁶⁷ The high dropout rate was primarily from noncompliance. Approximately 6.8% dropped out due to program dissatisfaction. Seventy-two percent achieved a reduction in their PASI scores within 6.2 average treatments, 35% achieved 90% reduction in an average 7.5 treatments. Treatments were scheduled twice weekly. After 10 or fewer treatments, 84 and 50 percent of patients achieved the outcomes of 75 percent or better and 90 percent or better clearing of plaques, respectively. This number of treatments was far fewer than that typically required of phototherapy (25 or more). Side effects of laser therapy included erythema and blistering; these were generally well tolerated, and no patient discontinued therapy because of adverse effects.⁶⁷

A large trial of 272 patients treated with cream psoralens combined with UVA irradiation (PUVA) showed there was no change in efficacy but patients went into remission in half the treatment time and with half the cumulative dose when excimer was added to the treatment regime.⁶⁸

Phototherapy Treatment for Pregnant Women

Narrowband ultraviolet B phototherapy with a wavelength of 311nm appears to be a safe and effective for treating pregnant women with psoriasis.^{79,80} Localized disease has been treated safely and effectively by 308nm laser.⁸⁰ There is minimal information regarding the use of phototherapy or psoralen therapy in breastfeeding women. UpToDate authors indicate “women with moderate to severe symptoms, we suggest narrow band ultraviolet B phototherapy rather than oral therapies because of the safety and efficacy of phototherapy in pregnancy.”⁷⁸

Hayes, Cochrane, UpToDate.

Hayes published a Directory report in 2013 entitled Laser Therapy for Psoriasis that indicates a small body of primarily low-quality evidence demonstrates a beneficial effect of treatment with excimer laser and pulsed dye laser (PDL) therapy for patients with plaque psoriasis. The magnitude of change in plaque lesion clearance was relatively large, and was \geq 40% for both types of lasers, but change in clearance for the excimer laser did surpass 70% in several studies. The benefit might differ for various forms of psoriasis. Given the short follow-up period of most of the studies, it is unknown whether benefits are maintained long term. Short-term benefits were maintained for 6 months (excimer) to 1 year (PDL) for some plaque psoriasis patients; but for nail psoriasis, plaques recurred with continued PDL therapy beyond 3 months. Regardless of laser type, the complications reported in the reviewed studies were generally mild and transient and included hyperpigmentation, erythema, and/or blistering of the skin. While laser therapy for psoriasis appears to be a relatively safe procedure, clinicians are cautioned on use of targeted phototherapy for patients with photosensitivity disorders. There were very few studies comparing laser therapy with standard treatments. The preliminary evidence suggests comparable results for excimer laser therapy and excimer lamp, non-laser ultraviolet B (UVB) phototherapy, or

psoralen plus ultraviolet A (PUVA) treatment, and for PDL therapy and UVB phototherapy. The addition of topical treatment to excimer laser might reduce treatment time. Evidence from 1 study suggests that excimer laser might be more effective than PDL in the short term.⁹⁸

Hayes published a Health Technology Brief entitled Home Ultraviolet B Phototherapy for Psoriasis in 2012. The literature search in the report identified one multicenter randomized controlled study, one 2-phase prospective comparative study, and three prospective case series studies assessing the efficacy and safety of home UVB phototherapy for psoriasis. An additional prospective case series separately reported on patient adherence to home phototherapy in patients from one of the reviewed prospective case series. The evidence suggests that home UVB therapy for psoriasis is effective and well tolerated, and that patients generally adhered to treatment. The overall quality of the body of evidence is low. The studies lacked adequate controls and long-term follow-up data; some did not report the statistical significance of key findings. Additional well-designed controlled studies are needed to further assess the short- and long-term safety and efficacy of UVB therapy in the home, compare home UVB therapy with other second-line treatments for psoriasis, and compare home UVB monotherapy with combination therapies.⁸⁶

Professional Organizations

The Agency for HealthCare Research and Quality (AHRQ) (2012)⁸⁴ published an evidence-based comparative effectiveness review of biological and nonbiologic systemic agents and phototherapy for the treatment of chronic plaque psoriasis. Included studies had an adult patient population (age ≥ 18 years) with chronic plaque psoriasis (or psoriasis vulgaris), or evaluated and reported data on a subpopulation of adult patients with chronic plaque psoriasis. No randomized controlled trials and three observational studies (one fair and two poor in quality) compared systemic biologics with phototherapy. Follow-ups ranged from 10.3–12 weeks. The studies primarily included small international patient populations ($n < 200$). Statistical pooling of the data was not possible. AHRQ concluded that overall, there was insufficient evidence to determine the comparative effectiveness of individual therapies compared with each other between the specified classes. The comparisons made (adalimumab, etanercept, infliximab, and ustekinumab versus NB-UVB and etanercept and infliximab versus PUVA) revealed that there was insufficient evidence to evaluate health-related quality of life or other final health outcomes. There was also insufficient evidence to evaluate body surface area, Psoriasis Area and Severity Index (PASI), Physician's Global Assessment (PGA) score, psoriatic arthritis pain and pruritus.

The American Academy of Dermatology's (AAD) (2010) guidelines of care for the management of psoriasis and psoriatic arthritis⁸³ recommendations include UVB phototherapy, PUVA and excimer laser therapy. According to AAD, UVB phototherapy is safe and effective, and nbUVB phototherapy is generally preferable and has improved efficacy compared to bbUVB phototherapy. UVB phototherapy can be given in the office or at home. PUVA is also effective and may result in long remissions, but may increase the risk for squamous cell carcinoma and malignant melanoma. The duration of treatment using phototherapy or photochemotherapy varies depending on the type of psoriasis, skin type, ultraviolet dosing, and whether nbUVB (e.g., 15–20 treatments), bbUVB (e.g., 20–25 treatments), or topical or systemic PUVA is used. Improvement may be seen within 2–4 weeks and 8–40 treatments. AAD recommended excimer laser for the treatment of mild, moderate or severe psoriasis with less than 10% body surface area involvement. Initial dosage depends on the skin type and plaque characteristics and thickness. Treatment is typically administered two to three times a week until the condition clears (average of 10–12 weeks). Mean remission time is reported to be 3.5–6 months.

The National Psoriasis Foundation Medical Board⁸⁵ identified two tiers for categorizing severity of disease in an evidence-based clinical consensus document. Localized therapy, which includes topical treatments and excimer laser treatments, is recommended for patients with psoriasis that affects less than 5% body surface area (BSA). Systemic therapy and/or phototherapy, which includes broad and narrowband phototherapy, photochemotherapy (PUVA), systemic

agents, and biologics is recommended for patients with psoriasis affecting greater than 5% BSA; for those with less than 5% BSA affected in vulnerable areas, such as the face, genitals, hands or feet; and for other forms of psoriasis, including but not limited to erythrodermic, pustular and guttate. In addition, patients with limited affected areas and inadequate response to localized therapy or impairment in physical or mental functioning should also be considered candidates for systemic and/or phototherapy treatment.

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
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)
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	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
696.1	Other psoriasis
ICD-10	Description
L40.8	Other psoriasis
L40.9	Psoriasis unspecified

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

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