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**Title:**

Targeted Phototherapy for Psoriasis

**Number:**

THE801.025

**Effective Date:**

10-15-2007

**Legislation:**

**ILLINOIS:** None

**NEW MEXICO:** None

**OKLAHOMA:** None

**TEXAS:** None

**FEDERAL (applies to all Plans):** None

**Contract:**

Each benefit plan or contract defines which services are covered, which are excluded, and which are subject to dollar caps or other limits. Members and their providers have the responsibility for consulting the member's benefit plan or contract to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between a Medical Policy and a member's benefit plan or contract, the benefit plan or contract will govern.

**Coverage:**

Targeted phototherapy **may be considered medically necessary** for the treatment of moderate to severe psoriasis comprising less than 20% body area for which narrowband ultraviolet B (NB-UVB) or psoralen plus ultraviolet A (PUVA) are indicated.

Targeted phototherapy **may be considered medically necessary** for the treatment of mild to moderate psoriasis that is unresponsive to conservative treatment.

Targeted phototherapy **is considered experimental, investigational and unproven** for the following:

- first-line treatment of mild psoriasis;
- treatment of generalized psoriasis or psoriatic arthritis;
- all other dermatologic conditions and diagnoses, including but not limited to:
  1. acne vulgaris,
  2. alopecia areata,
  3. atopic dermatitis,
  4. atopic eczema,
  5. hypertrichosis,
  6. keloids,
  7. leukoderma
  8. rosacea,

9. vitiligo, and/or
10. warts.

**Codes:**

CPT Codes:	HCPCS Codes:
96922  , 96920, 96921	None

ICD-9 Diagnosis Codes:	ICD-9 Procedure Codes:
696.0, 696.1, 696.2	Refer to the ICD-9-CM manual

**Description:**

Psoriasis is a lifelong, noncontagious skin disease that most commonly appears as raised, red patches or lesions covered with a silvery white buildup of dead skin cells, called scale. Psoriasis is typically defined as mild, moderate, or severe.

The National Psoriasis Foundation (NPF) defines severity levels as:

- mild psoriasis, affecting <3% of the body;
- moderate psoriasis, affecting 3-10% of the body;
- severe psoriasis, affecting >10% of the body.

The palm of the hand equals 1% of the skin. The NPF also states that the severity of psoriasis is also measured by how psoriasis affects a person's quality of life. Psoriasis can have a serious impact even if it involves a small area, such as the palms of the hands or soles of the feet.

The American Academy of Dermatology (AAD) Consensus Statement on Psoriasis Therapies states that severity is a qualitative decision based on overall judgment as determined by history and examination. The AAD also states that mild psoriasis, based on limited body surface area involvement may still warrant phototherapy or systemic therapy if it is not responsive to topicals, or if there is disruption of daily activities and/or employment.

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 PUVA and both broadband and narrowband ultraviolet B (BB-UVB and NB-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 (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, which are considered erythemogenic 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. In 2001, a XeCl excimer laser (XTRAC™ by PhotoMedex) 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 the XTRAC XL™ 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.

FDA 510(k) approval does not require data regarding clinical efficacy; essentially, these devices are considered a different technique for generating UVB light. The proposed advantage of a hand-held device is that it specifically targets individual lesions, thus limiting exposure to the surrounding normal tissues.

Targeted phototherapy may therefore allow higher dosages compared to a light box, which could result in fewer treatments to produce clearing. The original indication of the excimer laser was for patients with mild to moderate psoriasis, defined as involvement of less than 10% of the skin. Typically, these patients have not been considered candidates for light box therapy, since the risks of exposing the entire skin to the carcinogenic effects of UVB light may outweigh the benefits of treating a small number of lesions. Patients with mild localized psoriasis are treated primarily with topical therapy. A variety of agents may be used; calcipotriene (Dovonex®), tazarotene (Tazovac®), and fluocinonide (Lidex®) are examples.

**Rationale:**

A search of the MEDLINE database was conducted on the topic of targeted phototherapy of psoriasis. Articles published between 2001 (the date of the first targeted device approval) through August 2007 were reviewed.

Technical literature indicates that handheld NB-UVB delivery devices can be considered similar to conventional phototherapeutic lights since they produce wavelengths of light that are within the therapeutic range. Clinical guidelines from the British Association of Dermatologists state that panel irradiators and point sources are acceptable alternatives to whole-body cabinets or upright panels, with each light source having its advantages and disadvantages. Guidelines on the treatment of psoriasis from the American Academy of Dermatology also indicate that targeted phototherapy is an appropriate alternative to PUVA or UVB (with or without topical or oral retinoids) for the treatment of moderate to severe localized disease. Their guidelines do not recommend phototherapy for limited (mild) psoriasis, erythrodermic/generalized psoriasis or psoriatic arthritis.

**Clinical Efficacy**

Two blinded and controlled studies compared targeted UVB with standard phototherapy of psoriasis; both used equivalent starting doses and patches matched on either side of the body. One study compared a NB-UVB lamp with cream PUVA in ten subjects with palmoplantar psoriasis. The UVB lamp and PUVA-treated sides showed similar gradual clearing over the course of 20 treatments, reaching 64% clearance at the end of the five-week treatment period. In the other blinded study the excimer laser was compared to full body NB-UVB in 16 patients with psoriasis vulgaris. At the end of 20 treatments the psoriasis area and severity scores (PASI) were equally reduced on the two sides, from a baseline of 11.8 to 6.3 for laser and from 11.8 to 6.9 for non-targeted NB-UVB. A patch comparison in 15 patients with stable plaque also found no difference in efficacy between the 308-nm laser, the 308-nm excimer lamp, and standard TL-01 lamps.

A multicenter open trial of 124 patients with mild to moderate psoriasis reported effective clearance of lesions among the 80 patients who completed XeCl laser treatment. Comparison of these results to historical controls found laser therapy to be more effective than placebo and comparable or more effective to other standard treatments for psoriasis. Controlled studies comparing targeted phototherapy with topical treatment for patients with mild disease are lacking.

## Treatment-resistant plaques

Clinical studies suggest that targeted phototherapy can be effective for treatment-resistant lesions. One controlled patch comparison reported effective clearing (PASI pre 6.2, PASI post 1.0) of treatment-resistant psoriatic lesions; six of the patients had previously received topical treatment, five had received conventional phototherapy, and three had received combined treatments including phototherapy. The same group reported that 12 of 13 subjects with "extensive and stubborn" scalp psoriasis (i.e., unresponsive to class I topical steroids used in conjunction with tar and/or zinc pyrithione shampoos for at least one month) showed clearing following treatment with the 308-nm laser. In a recent open trial from Europe, 44 of 54 patients with palmoplantar psoriasis resistant to combined phototherapy and systemic treatments were cleared of lesions with only one NB-UVB lamp treatment per week for eight weeks.

## Dosing

Results suggest that targeted dosing may be more effective than dosing based on the minimal erythematous dose (MED) of unaffected skin. One study evaluated dosing in 163 patients with the XeCl laser. Initially, 120 patients with mild to moderate localized plaque were treated beginning at three times the MED of unaffected skin, increasing by one MED unless an erythematous reaction occurred on the psoriatic skin. Of the 102 patients who completed 13 treatment sessions, 87 had > 90% clearance of lesions. Based on the findings in the first treatment group, a second group of 43 patients had treatment initiated at a MED level in accordance with the epidermal thickness of the psoriatic lesion, as determined by ultrasound, to maximize therapeutic effect while minimizing adverse side effects; 34 of 40 patients (83.7%) achieved clearance of lesions in only  $7.07 \pm 2.15$  sessions, resulting in a lower cumulative dose of UVB. A patch comparison (described above) found no difference in efficacy between targeted laser, targeted lamp, or standard TL-01 lamps when all were administered at the standard NB-UVB dose.

However, when the investigators used an accelerated dosing scheme to compare the two targeted devices (16 patients), clearance was achieved with fewer treatments and half the cumulative dose of the first regime. Thus, targeted phototherapy may allow higher (and more therapeutic) doses of light to be delivered to the lesion in comparison with dosing based on the erythematous dose of unaffected skin.

Controlled studies based on the MED of the patch/lesion are needed to determine the most effective treatment and maintenance schedules.

There is concern for the possibility of cancer induction with long-term UVB treatment. PUVA has been associated with increased cancer risk; there is currently no evidence that supports increased risk following extended UVB treatment. Given the higher MED of plaques and reduced exposure of unaffected skin, targeted NB-UVB may have an improved benefit/risk ratio over non-targeted phototherapy for localized psoriasis.

There is currently no evidence to recommend any one targeted or non-targeted NB-UVB device over another. Devices with smaller focal areas may result in more frequent blistering due to "tiling," the practice of overlapping adjoining treatment zones.

The literature 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.

Based on this review, evidence is lacking for the use of targeted phototherapy for the first-line treatment of mild psoriasis or for the treatment of generalized psoriasis, psoriatic arthritis, or other dermatologic conditions.

**Pricing:**

In 2002, CPT established separate codes (96920-96922) that describe ultraviolet light laser treatment for inflammatory disease (psoriasis) according to the surface area of skin treated (total area is less than 250 cm<sup>2</sup>, is equal to 250 sq cm-500 cm<sup>2</sup>, or is over 500 cm<sup>2</sup>).

The laser treatment codes are distinct from codes that describe the dermatological use of ultraviolet light, also known as actinotherapy (96900), and photochemotherapy (96910-96913).

Established treatments for psoriasis include use of topical ointments and ultraviolet light ("light lamp") treatments. Lasers and targeted UVB lamps are considered to be equivalent devices; targeted ultraviolet devices are comparable to ultraviolet light panels for treatment purposes. First-line treatment of UV-sensitive lesions may involve around 6-10 office visits, treatment of recalcitrant lesions may involve around 24-30 office visits. Maintenance therapy or repeat courses of treatment may be required.

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**Related Documents:**

**MED201.023, Dermatoscopy**

**RAD602.017, Ultrasonic Evaluation of Skin Lesions**

**THE801.027, Photodynamic Therapy (PDT) for the Treatment of Actinic Keratoses (AK) and Other Skin Lesions**

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