



2.01.47 Targeted Phototherapy for Psoriasis

Section
Medicine

Subsection

Issue
6:2007

Original Policy Date
11/20/01

Last Review Status/Date

Reviewed with literature search/12:2007

Disclaimer

Our medical policies are designed for informational purposes only and are not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

Description

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

Original NB-UVB devices consisted of a Phillips TL-01 fluorescent bulb with a maximum wavelength

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

This type of FDA 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 (1, 2).

Policy

Targeted phototherapy may be considered **medically necessary** for the treatment of moderate to severe psoriasis comprising less than 20% body area for which NB-UVB or 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 **investigational** for the first-line treatment of mild psoriasis.

Targeted phototherapy is considered **investigational** for the treatment of generalized psoriasis or psoriatic arthritis.

Policy Guidelines

Although disease severity is minimally defined by body surface area (mild psoriasis affects less than 5% of the body's surface area, moderate psoriasis affects 5-10%, and severe disease affects more than 10% 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. (3-5) 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. While the psoriasis area and severity index (PASI) may be used as an outcome measure in clinical research, clinical assessment of disease severity is qualitative.

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 less than 250 sq cm, 250 sq cm-500 sq cm, over 500 sq cm).

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.

Benefit Application

BlueCard/National Account Issues

Some state or federal mandates (e.g., FEP) prohibit Plans from denying FDA-approved technologies as investigational. In these instances, Plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

Targeted phototherapy has not been shown to be superior to conventional phototherapy. Therefore, benefit or contract language describing the "least costly alternative" may be applied.

Specific contract language regarding definitions of cosmetic/reconstructive services may apply. (Refer to policy No. 10.01.09 for further discussion.)

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 November 2006 were reviewed.

Technical literature indicates that handheld narrowband UVB (NB-UVB) delivery devices can be considered similar to conventional phototherapeutic lights since they produce wavelengths of light that are within the therapeutic range. (6) 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. (7) 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.(3) 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. (8, 9) One study compared a NB-UVB lamp with cream PUVA in 10 subjects with palmoplantar psoriasis. (8) 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 5-week treatment period. In the other blinded study the excimer laser was compared to full body NB-UVB in 16 patients with psoriasis vulgaris. (9) At the end of 20 treatments the PASI scores 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. (10)

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. (11) 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 (12) 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; 6 of the patients had previously received topical treatment, 5 had received conventional phototherapy, and 3 had received combined treatments including phototherapy.

(13) 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 1 month) showed clearing following treatment with the 308-nm laser. (14) 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 1 NB-UVB lamp treatment per week for 8 weeks. (15)

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 (chronic plaque psoriasis and < 20% body surface area affected) with the XeCl laser. (16) Initially, 120 patients with mild to moderate localized plaque were treated beginning at 3 times the MED of unaffected skin, increasing by 1 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 ± 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. (10) 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. (17) 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 or psoriatic arthritis.

2007 Update

A search of the MEDLINE database for the period of December 2006 to November 2007 did not identify any evidence that would alter the conclusions reached above. Studies from outside of the U.S./European Union are examining the efficacy of targeted TL-01 lamps. One study conducted a left-to-right comparison of local NB-UVB vs. PUVA paint for palmoplantar psoriasis (3 times per week for 9 weeks) in a cohort of 25 patients. (18) The mean severity index improved by 61% with local NB-UVB and 85% with PUVA paint; one patient dropped out of the study because of a phototoxic reaction in

the PUVA-paint-treated side. Another study assessed the efficacy of targeted NB-UVB (mercury lamp) alone or in combination with 8-methoxypsoralen cream (8-MOP) in stable psoriatic plaques. (19) For the 10 patients (83%) who completed the study, combined treatment resulted in greater clearance (area under the curve of 51 vs. 37) and longer remission (8 vs. 5 weeks). No studies were identified that compared different types of targeted or non-targeted UVB devices; therefore, the policy statements are unchanged.

References:

1. Dovonex® (Westwood Squibb): Package insert
2. Tazorac® (Allergen): Package insert
3. Callen JP, Krueger GG, Lebwohl M et al. AAD consensus statement on psoriasis therapies. *J Am Acad Dermatol* 2003; 49(5):897-9.
4. Finlay AY. Current severe psoriasis and the rule of tens. *Br J Dermatol* 2005; 152(5):861-7.
5. Lebwohl MG, van de Kerkhof P. Psoriasis. In *Treatment of Skin Disease: Comprehensive Therapeutic Strategies*. Lebwohl MG, Heymann WR, Berth-Jones J et al., eds. London: Mosby, 2005; pps 550-7.
6. Hamzavi I, Lui H. Using light in dermatology: an update on lasers, ultraviolet phototherapy, and photodynamic therapy. *Dermatol Clin* 2005; 23(2):199-207.
7. Ibbotson SH, Bilisland D, Cox NH et al.; British Association of Dermatologists. An update and guidance on narrowband ultraviolet B phototherapy: a British Photodermatology Group Workshop Report. *Br J Dermatol* 2004; 151(2):283-97.
8. Neumann NJ, Mahnke N, Korpusik D et al. Treatment of palmoplantar psoriasis with monochromatic excimer light (308-nm) versus cream PUVA. *Acta Derm Venereol* 2006; 86(1):22-4.
9. Goldinger SM, Dummer R, Schmid P et al. Excimer laser versus narrow-band UVB (311 nm) in the treatment of psoriasis vulgaris. *Dermatology* 2006; 213(2):134
10. Kollner K, Wimmershoff MB, Hintz C et al. Comparison of the 308-nm excimer laser and a 308-nm excimer lamp with 311-nm narrowband ultraviolet B in the treatment of psoriasis. *Br J Dermatol* 2005; 152(4):750-4.
11. Feldman SR, Mellen BG, Housman TS et al. Efficacy of the 308-nm excimer laser for treatment of psoriasis: results of a multicenter study. *J Am Acad Dermatol* 2002; 46(6):900-6.
12. Rodewald EJ, Housman TS, Mellen BG et al. The efficacy of 308nm laser treatment of psoriasis compared to historical controls. *Dermatol Online J* 2001; 7(2):4. Available online at www.dermatology.cdlib.org/DOJvol7num2/original/psoriasis2/feldman.html
13. Taneja A, Trehan M, Taylor CR. 308-nm excimer laser for the treatment of psoriasis: induration-based dosimetry. *Arch Dermatol* 2003; 139(6):759-64.
14. Taylor CR, Racette AL. A 308-nm excimer laser for the treatment of scalp psoriasis. *Lasers Surg Med* 2004; 34(2):136-40.
15. Nistico SP, Saraceno R, Stefanescu S et al. A 308-nm monochromatic excimer light in the treatment of palmoplantar psoriasis. *J Eur Acad Dermatol Venereol* 2006; 20(5):523-6.
16. Gerber W, Arheilger B, Ha TA et al. Ultraviolet B 308-nm excimer laser treatment of psoriasis: a new phototherapeutic approach. *Br J Dermatol* 2003; 149(6):1250-8.
17. Lee E, Koo J, Berger T. UVB phototherapy and skin cancer risk: a review of the literature. *Int J*

Dermatol 2005; 44(5):355-60.

Codes	Number	Description
CPT	96900	Actinotherapy (ultraviolet light)
	96920	Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm
	96921	Total area 250–500 sq cm
	96922	Total area greater than 500 sq cm
ICD-9 Procedure		
ICD-9 Diagnosis	696.1	Psoriasis
HPCPS		
Type of Service	Medicine	
Place of Service	Outpatient	

Index

Laser Treatment, Psoriasis
 Photomedex; Laser Treatment of Psoriasis
 Psoriasis; Laser Treatment (Photomedex)
 XTRAC Laser, Psoriasis

Targeted Phototherapy, Psoriasis
 Psoriasis; Targeted Phototherapy

Policy History

Date	Action	Reason
11/20/01	Add to Medicine section	New policy
12/18/02	Replace policy	Update CPT codes only
04/29/03	Replace policy	Policy updated; policy statement unchanged, references new CPT codes added.
11/9/04	Replace policy	Literature review update for the period of 2003 through August 2004; references added. Policy statement unchanged
09/27/05	Replace policy	Literature review updated for the period of August 2004 through July 2005; reference number 12 added. Policy statement unchanged
4/25/06	Replace policy – error correction only	Reference 8 corrected.

12/12/06	Replace policy	Literature review conducted for the period of 2001 through November 2006; policy revised and rewritten; 7 references added; policy statements revised to include medically necessary and investigational uses
12/13/07	Replace Policy	Policy updated with literature review; references 4, 5 and 18, 19 added; severity definitions added to policy guidelines; policy statement clarified.
