



# CIGNA MEDICAL COVERAGE POLICY

The following Coverage Policy applies to all health benefit plans administered by CIGNA Companies including plans formerly administered by Great-West Healthcare, which is now a part of CIGNA.

**Subject Laser Therapy and Grenz Ray Therapy for Treatment of Psoriasis**

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## Hyperlink to Related Coverage Policies

- Adalimumab (Humira®)
- Alefacept (Amevive®)
- Etanercept (Enbrel®)
- Infliximab (Remicade®)
- Photodynamic Therapy for Dermatologic Conditions
- Phototherapy, Photochemotherapy, and Excimer Laser for Dermatologic Conditions

## INSTRUCTIONS FOR USE

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## Coverage Policy

**CIGNA covers targeted laser therapy using an excimer laser\* (i.e., 308 nanometers[nm]) as medically necessary for the treatment of localized, plaque psoriasis refractory to conservative treatment with topical agents and/or phototherapy.**

**CIGNA does not cover ANY of the following therapies for the treatment of psoriasis, because each is considered experimental, investigational or unproven (this list may not be all-inclusive):**

- targeted laser therapy for the treatment of generalized psoriasis (i.e., large area, wide area)
- laser therapy using EITHER of the following lasers:
  - flashlamp-pumped pulsed dye laser (FLPDL)
  - erbium:yttrium-aluminum-garnet (Er:YAG) laser
- Grenz ray therapy

## General Background

Plaque psoriasis, also called psoriasis vulgaris, is the most common type of psoriasis and is characterized by raised, thickened patches of inflamed skin, called plaques, which are covered with silvery-white scales. Associated symptoms may include dry, cracked skin that bleeds, itching, burning or soreness. Psoriasis is usually diagnosed by clinical examination and visual inspection; when the diagnosis is uncertain, skin biopsy may be performed.

Various methods can be utilized to determine the severity of psoriasis. Despite some reported variability among authors, the Psoriasis Area and Severity Index (PASI), is reported as the most frequently used measurement tool for psoriasis and combines the extent of psoriasis lesions and the area affected into a single score of severity which ranges from 0 to 72. The PASI tool is used primarily in research settings to assess effectiveness of treatment, and not in clinical practice however (Langley, Ellis, 2004). Other tools used to assess severity of disease, (particularly those with milder disease), include the Physicians Global Assessment (PGA) and target plaque scores, together with determination of body surface area (BSA) involvement. When using the PGA tool the physician assigns a single estimate of severity; usually a 7-point scale from clear to severe (Menter, et al., 2008).

In clinical practice, the severity of a patient's psoriasis is generally evaluated by combining the objective assessment (e.g. body surface area (BSA) of involvement, disease location, thickness) and subjective assessment of the physical, financial, and emotional impact of the disease on the patient's life. This subjective assessment is combined with the physician's global assessment of psoriasis to determine psoriasis severity and appropriate therapy. Frequently, the severity of psoriasis is graded as mild, moderate or severe, although there is no agreement regarding what represents mild, moderate or severe cases. The National Psoriasis Foundation has proposed methods for classifying severity of disease and up until recently, classified mild psoriasis as affecting less than 3% of the body, moderate affecting 3–10% of the body and severe psoriasis affecting more than 10% of the body. One percent of body surface area (BSA) is generally described as the patient's open hand with fingers tucked together and thumb tucked to the side (i.e., Lattice-System PGA). In 2007 the National Psoriasis Foundation Medical Board reviewed the existing psoriasis severity criteria and other published psoriasis consensus statements (Pariser, et al., 2007) and modified how psoriasis was initially classified. Using current standards of care and expert opinion, the committee recommended a two-tiered system that categorized patients with plaque psoriasis and more accurately reflected how patients are treated. The two tier system classifies patients as candidates for localized therapy or candidates for systemic therapy and/or phototherapy. Localized disease is described as that which is restricted to a well defined area and can be treated with the use of topical agents, although the definition of localized disease varies in the medical literature.

Psoriasis severity is also measured by the impact on quality of life—some forms, such as that which occurs on the palms and soles of the feet or hands, on the scalp, and in skin folds, can be resistant to treatment even though they are not categorized as severe.

### **Treatment Options**

The major goals of psoriasis treatment are to reduce inflammation and to control the excessive proliferation and shedding of the skin cells. Treatment choice depends on the type and severity of disease and the patient's health, lifestyle and age. Localized disease can often be treated with topical therapies whereas generalized or refractory psoriasis may require oral medications, phototherapy or photochemotherapy. Appropriate therapies include, but are not restricted to, topical corticosteroids, topical cholecalciferol analogs, combinations of these two therapies, topical retinoids, tar preparations, anthralin, keratolytics, and excimer (UV-B) laser treatments. Systemic therapy and/or phototherapy (including broad and narrowband), photochemotherapy (PUVA), systemic agents, and biologics, is recommended for patients with psoriasis affecting greater than 5% BSA and for those with less than 5% BSA affected in vulnerable areas (e.g., face, genitals, hands or feet), and for other forms of psoriasis, including erythrodermic, pustular, and guttate. In addition, patients with limited affected areas and inadequate response to localized therapy or impairment in physical or mental functioning are also considered candidates for systemic and/or phototherapy treatment. Grenz ray therapy has been investigated as a possible treatment option for psoriasis. Improvement in health outcomes have been reported for the treatment of psoriasis utilizing laser therapy in which high-intensity light is used to treat localized lesions (targeted UV therapy), sparing the surrounding tissue.

Targeted laser therapy has been recommended as a treatment modality for certain types of psoriasis that are not responsive to standard therapies. Surgical lasers work by producing intense beams of virtually nondivergent light that can cut, seal and vaporize abnormal skin tissues. Various types of lasers have been utilized as

alternatives to UVA or UVB phototherapy involving whole body exposure for the treatment of localized plaque psoriasis in an attempt to decrease the risk of complications, particularly sunburn-like reactions and skin cancer, and to improve outcomes for patients with disease that is refractory to standard local therapies and for whom systemic therapy may be inappropriate. The types of lasers used include the flashlamp-pumped pulsed dye laser (FLPDL), the xenon-chloride (XeCl) excimer laser and the high-powered erbium:yttrium-aluminum-garnet (Er:YAG) laser, each of which exerts its therapeutic effects by a different mechanism (Boehncke, et al., 1999; Acland and Barlow, 2000; Asawanonda, et al., 2000; Hern, et al., 2001; AAD, 2003; ASDS, 2003; NIAMS, 2003).

Each laser delivery method employs a slightly different protocol although lasers deliver radiation to the psoriatic lesions and not to uninvolved skin. Laser devices have maximal field sizes through which radiation is delivered. For example, the FLPDL and Er:YAG laser deliver radiation to a 5 mm diameter area, while the XeCl excimer laser treats an area 2.54 cm in diameter. During a typical treatment session, the laser beam is focused on contiguous areas until the entire lesion has been lasered. Single or multiple treatments may be administered at fixed or escalating doses; it can take several months before clearing is achieved. Antibiotic ointment or emollients may be applied to the treatment site.

Grenz ray therapy is a form of ionizing radiation that has been investigated for a variety of inflammatory skin disorders, including, but not limited to, psoriasis. The rays have a very low penetrative power and do not extend deeply in the dermis of the skin (National Institute for Health and Clinical Excellence [NIH], 2007). Treatment is typically provided in an outpatient setting; a Grenz ray machine is used to direct the rays toward an affected area of about 10 to 20cm. A cone can be used to restrict exposure to targeted areas as necessary. Adverse events associated with Grenz ray therapy include non-melanoma skin cancer, erythema, and pigmentation changes. Some authors have reported that the use of Grenz ray therapy for treating psoriasis of the nail seems promising, but the evidence supporting efficacy is variable and serious potential side effects are associated with the treatment. Due to concerns regarding possible carcinogenicity, and the availability of other treatments deemed to be more efficacious, this form of treatment is not widely prescribed.

### **Literature Review**

Some studies evaluating targeted laser treatment of psoriasis included patients with chronic, stable, refractory plaque psoriasis, limited to certain areas of the body. The evidence in the peer-reviewed medical literature evaluating laser therapy for other types or extent of psoriasis is limited. Randomized controlled clinical trials evaluating laser therapy for psoriasis are scarce. In several of the studies the measured outcomes included complete or partial lesion clearing, indicated by improvements in the severity of the pretreatment erythema, scaling, induration, and lesion thickness in addition to the global score (i.e., a summary score of the aforementioned outcomes). The fact that different authors have used different systems to score psoriasis severity both before and after therapy hampers the ability to compare data across studies. Clinical examination, visual inspection, comparison of pre- and post-treatment photographs, histological examination of biopsy specimens, and microscopic visualization of the psoriasis lesions have all been assessed as outcomes of this treatment.

**XeCl Excimer Laser Therapy:** Evidence suggests narrowband UVB is more effective than broadband UVB (Menter, et al., 2010; Habif, 2004), and approaches PUVA in efficacy for the treatment of psoriasis in some patients (Ibotson, et al., 2004; Hamzavi and Lui, 2005). The XeCl excimer laser emits energy at a wavelength of 308 nm, which is similar to the wavelength emitted by narrow-band UVB radiation, 311 nm. This type of laser has been evaluated as an alternative to UVB phototherapy for irradiating psoriatic lesions. Several excimer lasers have received 510(k) approval from the U.S. Food and Drug Administration (FDA) for the treatment of psoriasis and include, but are not limited to, the Surgilight EX-308 excimer laser (Surgilight, Inc., Orlando, FL) the XTRAC™ excimer laser (Photomedex, Carlsbad, CA), a handheld XeCl device, and BClear™ Targeted PhotoClearing System (Lumins, Inc., Pleasanton, CA).

While excimer laser therapy may be considered a type of narrow-band UVB therapy, the recommended patient selection criteria are different. Goldinger et al. (2006) reported that this modality is difficult to use when patients have widespread disease, because the laser has a 2 x 2 cm spot size, making treatments of large body areas difficult. UVB therapy may be used to treat disease that is too extensive for topical therapy. Excimer laser therapy is typically recommended for patients with localized disease and for patients who have failed prior topical therapy. After initial treatment, continued treatment sessions depend on documented, significant

improvement to the targeted area. Treatment sessions generally last for 10–13 treatments. If there is no improvement in severity, continued treatment sessions are not medically necessary.

Published evidence in the form of controlled clinical trials and both retrospective and prospective case series supports the safety and effectiveness of excimer laser treatment for mild to moderate psoriasis (Bonis, et al., 1997; Asawonda, et al., 2000; Feldman, et al., 2002; Rodewald, et al., 2002; Novák, et al., 2002; Trehan and Taylor, 2002; Taneja, et al., 2003; Kollner, et al., 2005; Pahlajani, et al., 2005; Taibjee, et al., 2005; Goldinger, et al., 2006; Neuman, et al., 2006; Nistico, et al., 2006; Lapidoth, et al., 2007; He, et al., 2007; Trott, et al., 2008). Excimer laser therapy has been shown to improve response rates with some patients obtaining complete clearance and longer rates of remission when compared to other laser therapies and treatments. In addition, the American Academy of Dermatology (AAD) (Menter, et al., 2010) supports excimer laser therapy as a treatment for psoriasis.

ECRI (2005) conducted a systematic review of the peer-reviewed literature on laser therapy for treatment of psoriasis to determine whether laser therapy was safe and effective for patients with this condition. The review included data on excimer laser therapy in addition to pulsed dye laser therapy. While ECRI noted that excimer laser therapy resulted in short-term clinically significant benefits, ECRI stated the conclusion was supported by weak evidence and was insufficient to support improvement beyond two months post-treatment.

**FLPDL Therapy:** Another type of laser approved by the FDA for treating psoriasis is the flashlamp-pumped pulsed dye laser (FLPDL). The FLPDLs used in dermatology contain a rhodamine dye, which is excited by a xenon flashlamp to produce light at a wavelength of 585 nm in pulses of 450  $\mu$ sec (microseconds) for short-pulse FLPDL and 1500  $\mu$ sec for long-pulse FLPDL. This laser destroys vessels at a depth of 0.5–1.2 mm and photocoagulates vessels of  $\leq 100 \mu$ m (micrometers) in diameter. The damage is confined to the superficial dermal blood vessels (Hacker and Rasmussen, 1992; Katugampola, et al., 1995; Zelickson, et al., 1996; Acland and Barlow, 2000; ASDS, 2003).

Recommendations for the use of FLPDL for the treatment of localized, therapy-resistant plaque psoriasis remain controversial among authors. In a recent prospective study, Leeuw et al. (2006) evaluated the safety and efficacy of pulsed dye laser therapy for the treatment of psoriasis of the hands and feet. The study group included 41 patients treated with PDL (585 nm, 450  $\mu$ sec pulse duration) once every four to six weeks, in addition to calcipotriol ointment and salicylic acid as keratolytic agents between laser treatments. In all, 76% of the patients treated achieved more than 71% clearance after an average of 4.2 treatment sessions. In order to assess remission, follow-up was conducted until 36 months post-lesion clearance; the average duration of remission was 10.7 months for patients who achieved more than 71% improvement. Although promising, the study was limited by small sample size and concomitant use of keratolytic agents between treatments.

Erceg et al. (2006) compared the efficacy of the pulsed dye laser in the treatment of localized, recalcitrant plaque psoriasis with topical therapy using calcipotriol/betamethasone dipropionate (Dovobet<sup>®</sup>). In a left-right comparison, eight patients with recalcitrant psoriasis were treated with both calcipotriol/betamethasone dipropionate (CB) and pulsed dye laser. After four weeks of treatment with both laser and CB, the patients entered a follow-up period of eight weeks. Clinical efficacy was scored at baseline and at four and 12 weeks. With the exception of one patient who left the study due to pain associated with pulsed dye laser treatment, both treatments were well tolerated. The authors reported that after four weeks there was no statistically significant change in sum scores among both groups; however, there was a significant difference in the sum score 12 weeks after treatment in favor of the pulsed dye laser (62% vs. 19% reduction) when compared to week zero and week four. Scores for erythema declined significantly at week 12 in both groups. In the pulsed dye laser group, induration and desquamation scores were significantly reduced at week 12. The major side effect reported with pulsed dye laser was pain at the treated site. The pain scores declined after the second and third session of laser treatment. Four patients developed residual hyperpigmentation. Four of seven patients reached complete clearance of the psoriasis lesion eight weeks after the final laser treatment. After more than six months of follow-up, the four patients with a complete response to laser treatment still had clearance of treated plaque. The hyperpigmentation was still visible, although three of these patients required systemic treatment for an exacerbation of their psoriasis. Therefore, the follow-up observation on the plaque treated with laser was no longer reliable. Limitations of this study included small sample size and lack of blinding.

De Leeuw et al. (2009) prospectively studied the effects of narrowband UVB and pulsed dye laser in a comparative trial involving 27 subjects with plaque psoriasis. Four plaques were each treated with UVB, pulsed

dye laser, and UVB plus pulsed dye laser. Results were compared to a nontreated plaque. Clinical results were obtained using the PGA score 13 weeks after the initiation of treatment. Each treatment modality resulted in significant improvement in the PGA scores compared to baseline. There were no statistically significant differences between the three treatment modalities. The authors stated that in terms of response, the pulsed dye laser was statistically as effective as UVB treatment, although there was no synergistic effect of combining pulsed dye laser with UVB. Treatment with only pulsed dye laser resulted in minor side effects and appeared to be safe for plaque type psoriasis, although efficacy was limited to a subgroup of patients.

Norborio et al., (2009) compared clinical and immunohistological effects of pulsed dye laser on recalcitrant psoriasis (n=11). Clinical effects were assessed using the plaque severity score in which the mean percentage reduction was 42. The score differed significantly between untreated and treated plaques. For three patients plaques immediately recurred within one month following treatment, two patients were in complete remission for more than seven months, and four patients had partial remission. The authors also noted pulsed dye laser decreased the number of dermal papillary vessels, an important target of psoriasis, making pulsed dye laser a valid therapeutic approach for treatment.

ECRI (2005) conducted a systematic review of the peer-reviewed literature on laser therapy for treatment of psoriasis to determine whether laser therapy was safe and effective for patients with this condition. The review included data on excimer laser therapy in addition to pulsed dye laser therapy. ECRI determined the evidence was insufficient to determine whether pulsed dye laser led to clinically significant benefits among patients with mild to moderate psoriasis.

The National Psoriasis Foundation suggests pulsed dye laser therapy may achieve clearing of psoriasis lesions. However, few studies have supported a clinical benefit from pulsed dye laser therapy for the treatment for psoriasis with low clearance rates. The literature lends some support that applying keratolytic agents may improve outcomes when combined with PDL therapy. Nonetheless, there is insufficient evidence in the published, peer-reviewed scientific literature to allow strong conclusions regarding safety and efficacy, and generally authors agree that further well-designed, clinical trials are necessary before safety and long-term effectiveness can be established.

**Er:YAG Laser Therapy:** The Er:YAG laser is a high-powered laser that is used to treat wrinkles, mild surface scars and skin discolorations. It produces light at a wavelength of 2940 nm and has a depth of vaporization of 2–4  $\mu\text{m}$  for every 1  $\text{J}/\text{cm}^2$  (Joule per square centimeter) fluence.

Few studies have been conducted regarding the use of Er:YAG laser for the treatment of psoriasis. Boehncke et al. (1999) conducted a study comparing dermatome shaving to the application of an Er:YAG laser for the treatment of psoriasis. Interpretation of the results is limited by the very small size of the sample and by the paucity of clinical data. In this study, 75% of Er:YAG-treated lesions had a complete response, compared with 67% of lesions treated by dermatome shaving; however, 25% of the laser-treated lesions did not respond at all. Further clinical studies are needed to support the safety and efficacy of the Er:YAG laser for treatment of plaque psoriasis.

**Grenz Ray Therapy:** Grenz ray therapy has been proposed as a treatment option for psoriasis, more specifically for nail psoriasis and scalp psoriasis, particularly when the disease is refractory to other more convenient forms of treatment. The results of early clinical studies suggested that Grenz ray therapy might be effective, and when combined with topical corticosteroids treatment resulted in more rapid clearing of lesions (Lindelof, Johannesson, 1988). However, the published evidence generally involved small heterogeneous patient populations and measurement of short-term outcomes. There are concerns regarding the potential carcinogenicity associated with ionizing radiation.

In 2007 the National Institute of Health and Clinical Excellence (NICE), a United Kingdom organization that provides guidance for health technologies and clinical practice, published guidance for Grenz ray therapy for inflammatory skin conditions and concluded that the evidence is limited and difficult to assess due to heterogeneous study populations and small sample size. The guidance indicates carefully selected patients should only be offered therapy under research conditions.

Overall, evidence in the published medical literature evaluating the clinical utility of Grenz ray therapy and improved health outcomes is lacking and no strong conclusions can be made regarding safety and efficacy.

### Professional Societies/Organizations

A formal position statement regarding the treatment of psoriasis by the National Psoriasis Foundation (NSF) could not be found. However, the foundation acknowledges there are several treatment options available to control psoriasis and the goal is to find the treatment that works best and has the fewest side effects. Treatment options include topical therapies, systemic medications, phototherapies, and alternative approaches (e.g., dietary supplements, sunlight, herbal remedies) (NSF, 2007). According to NSF, laser treatment may take four to 10 sessions to achieve improvement; the recommended frequency of treatments is two treatments per week with 48 hrs between treatments.

The National Psoriasis Foundation Medical Board developed two tiers for categorizing severity of disease. Localized therapy, which includes topical treatments and excimer laser treatments, is recommended for patients with psoriasis that affects less than 5% 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 (Pariser, et al., 2007).

The American Academy of Dermatology (AAD) published guidelines of care for the management of psoriasis and psoriatic arthritis with phototherapy and photochemotherapy (Menter, et al., 2010). According to the guidelines, UVB is safe, effective, and cost-effective. Narrowband UVB is more effective than broadband UVB. Targeted laser therapy using excimer laser is indicated for adult and pediatric patients with mild, moderate or severe psoriasis with less than 10% BSA involvement. According to the guidelines, the frequency of laser treatment with excimer laser is 2-3 times weekly with a minimum of 48 hrs between treatments; an average of 10-12 treatments is usually needed. Although not commonly used and studies are limited, Grenz ray therapy may be an alternative to UV light therapy for localized, recalcitrant areas (e.g., scalp, palms) in situations where UV light is not feasible or psoriasis is unresponsive to conventional treatments. The AAD does not recommend phototherapy for patients with mild localized psoriasis whose disease can be controlled with topical medications.

### Summary

There is evidence in the published, peer-reviewed scientific literature to indicate that excimer laser therapy can improve clinical outcomes and produce complete or partial responses with minimal complications in a subset of patients with localized, refractory plaque psoriasis when more conservative treatment has failed. Published evidence supporting the use of the flashlamp-pumped pulsed dye, laser, high-powered erbium:ytrium-aluminum-garnet (Er:YAG) laser and Grenz ray therapy is insufficient to demonstrate that these methods are viable treatment options for psoriasis outside of the investigational setting. Targeted laser therapy has not been proven effective for generalized psoriasis (i.e., large body area, wide area). Overall, studies lack the statistical rigor needed to determine the impact of these technologies on health outcomes. In general they had small sample sizes, lacked randomization and adequate controls, and involved short follow-up times. Moreover, few of the studies provided a rigorous comparison of these technologies with standard therapies for psoriasis, and few provided a direct comparison of the different laser types. Large well-designed clinical trials are needed to prove the short- and long-term safety and effectiveness of these modalities in the clinical setting; to establish optimal, laser-specific treatment protocols; to resolve the technical limitations of the technique; and to define appropriate patient selection criteria.

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### Coding/Billing Information

**Note:** This list of codes may not be all-inclusive.

**Covered as medically necessary when used to report targeted laser therapy using an excimer laser (i.e., 308 nanometers[NM]) for the treatment of localized plaque psoriasis:**

CPT <sup>®</sup> * Codes	Description
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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

ICD-9-CM Diagnosis Codes	Description
696.1	Psoriasis and similar disorders; Other psoriasis
696.8	Psoriasis and similar disorders; Other

**Experimental, investigational or unproven and not covered when used to report Grenz ray therapy for the treatment of psoriasis:**

CPT <sup>®*</sup> Codes	Description
77401	Radiation treatment delivery, superficial and/or ortho voltage
77499	Unlisted procedure, therapeutic radiology treatment management

**\*Current Procedural Terminology (CPT<sup>®</sup>) © 2010 American Medical Association: Chicago, IL.**

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## Policy History

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<b>Pre-Merger Organizations</b>	<b>Last Review Date</b>	<b>Policy Number</b>	<b>Title</b>
CIGNA HealthCare	3/15/2008	0062	Laser Therapy and Grenz Ray Therapy for Treatment of Psoriasis
Great-West Healthcare	5/16/2006	06.341.01	Laser Therapy for Psoriasis

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