Pulsed Dye Laser Treatment

Number: 0559

Policy

I. Aetna considers pulsed dye laser treatment medically necessary for any of the following conditions:

A. Genital warts when home therapy with either podophyllotoxin or imiquimod has failed; or

B. Granuloma faciale; or

C. Infantile hemangiomas (see CPB 0817 - Lymphangioma and Infantile Hemangioma (../800_899/0817.html)); or

D. Keloids or other hypertrophic scars which are secondary to an injury or surgical procedure and either criterion below is met (see CPB 0031 - Cosmetic Surgery (../1_99/0031.html)):

- Causes significant pain requiring chronic analgesic medication; or
- Results in significant functional impairment; or

E. Mild-to-moderate localized plaque psoriasis when criteria are met in CPB 0577 - Laser Treatment for Psoriasis and Other Select Skin Conditions (0577.html); or

F. Multiple, superficially located glomangiomas in the face

Policy History

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Review History

Definitions

Additional Information

Clinical Policy Bulletin Notes
and neck, where surgical excision is not practical; or

G. Port wine stains and other hemangiomas when lesions are located on the face and neck (see CPB 0031 - Cosmetic Surgery (../1_99/0031.html)); or

H. Pyogenic granuloma in the face and neck; or

I. Verrucae (warts) after at least two of the following conventional therapies have been tried and failed: topical chemotherapy, curettage, electrodesication and cryotherapy.

II. Aetna considers the use of the pulsed dye laser cosmetic for any of the following conditions (see CPB 0031 - Cosmetic Surgery (../1_99/0031.html)):

- Dyschromia (caused by cafe au lait spots, rashes, sunburn/sun tan); or
- Removal of hair for pseudofolliculitis barbae or follicular cysts; or
- Removal of spider angiomata; or
- Removal of telangiectasias; or
- Rosacea (see CPB 0547 - Rosacea (0547.html)).

III. Aetna considers the use of the pulsed dye laser experimental and investigational for all other indications because of insufficient evidence in the peer-reviewed literature, including any of the following conditions:

- Active acne
- Angiokeratoma of the lower extremities
- Balanitis xerotica obliterans
- Basal cell carcinoma
- Cutaneous amyloidosis
- Cutaneous leishmaniasis
- Darier disease (also known as Darier-White disease or keratosis follicularis)
- Dyshidrotic eczema
- Dysphonia
- Glottic leukoplakia
- Granulation tissue
Granuloma annulare
Hailey-Hailey disease
Hereditary hemorrhagic teleangiectasia
Hidradenitis suppurativa
Hyper-vascularity of the perineum and genitalia
Lymphangioma
Microcystic lymphatic malformations
Molluscum contagiosum
Morphea (scleroderma of the skin)
Onychomycosis
Peri-implantitis Pilonidal disease
Pityriasis rubra pilaris
Xanthelasma palpebrum

Background
Laser therapy provides intense UVB light to a limited area of skin, providing the potential benefit of more rapid clinical response from targeted therapy while avoiding the side effects of ultraviolet light exposure to unaffected skin. The pulsed dye lasers emit short bursts of high-intensity yellow light (wavelength of 585 nm) that destroy the targeted tissue.

The pulsed dye laser (PDL) delivers energy at a wavelength and duration that has been optimized for the selective treatment of vascular lesions. It has been used in the treatment of warts, port wine stains, hemangiomas, hypertrophic scars, and telangiectasias. Pulsed dye lasers have been used as an alternative to surgical excision or carbon dioxide lasers. Examples of pulsed dye laser include, but may not be limited to, C-beam Pulsed Dye Laser System, PhotoGenica V Star and PhotoGenica V lasers.

The Food and Drug Administration (FDA) has cleared the PDL for use in treatment of warts, port-wine stains, hemangiomas, hypertrophic scars, and telangiectasias. The PDL has been shown to be effective in treating glomangiomas in the face and neck, as surgical excision may not be practical in these cosmetically sensitive areas. It has also shown to be effective in
removing pyogenic granulomas in cosmetically sensitive areas of the face and neck.

Charakida and colleagues (2004) reported that low-energy PDL therapy has been used, and seems to be a promising alternative that would allow the simultaneous treatment of active acne and acne scarring. However, the authors concluded that further studies are needed to clarify the role of phototherapy as a monotherapy or an adjuvant treatment in the current management of acne vulgaris.

In a randomized, controlled, clinical trial, Orringer and co-workers (2010) examined the effectiveness of photodynamic therapy (PDT) using 5-aminolevulinic acid (ALA) and PDL therapy in the treatment of facial acne (n = 44). Patients were randomized to receive 3 PDL treatments to one side of the face after a 60 to 90-min ALA application time, while the contralateral side remained untreated and served as a control. Serial blinded lesion counts and global acne severity ratings were performed. Global acne severity ratings improved bilaterally with the improvement noted to be statistically significantly greater in treated skin than in untreated skin. Erythematous macules (remnants of previously active inflammatory lesions) decreased in number in treated skin when compared with control skin and there was a transient but significant decrease in inflammatory papules in treated skin when compared with untreated skin. There were no other statistically significant differences between treated and untreated sides of the face in terms of counts of any subtype of acne lesion. Thirty percent of patients were deemed responders to this treatment with respect to improvement in their inflammatory lesion counts, while only 7% of patients responded in terms of non-inflammatory lesion counts. The authors concluded that PDT with the treatment regimen employed here may be beneficial for a subgroup of patients with inflammatory acne.

In a randomized, controlled, single-blinded trial, Karsai and associates (2010) evaluated the effectiveness of an adjuvant
PDL treatment when combined with a proven topical treatment [fixed-combination clindamycin 1 % - benzoyl peroxide 5 % hydrating gel (C/BPO)] for acne vulgaris. A total of 80 patients (38 males and 42 females, mean +/- SD age of 19.7 +/- 5.9 years) were randomized in a 1 : 2 ratio to receive C/BPO alone or in combination with PDL treatment (wavelength 585 nm, energy fluence 3 J cm(-2), pulse duration 0.35 ms, spot size 7 mm). Patients were evaluated at baseline and at 2 and 4 weeks after initial treatment. The primary end points were the Investigator’s Static Global Assessment (ISGA) score and lesion count; the secondary end point was the Dermatology Life Quality Index (DLQI). Both groups showed a significant improvement during observation [ISGA 27.1 % (C/BPO) and 24.6 % (C/BPO + laser), total lesion count 9.2 % and 9.0 %, inflammatory lesion count 36.3 % and 36.9 %, DLQI 54.5 % and 42.5 %], but there was no significant or otherwise appreciable difference between treatment modalities as far as the extent of improvement was concerned. Patients with more severe findings at baseline had a greater benefit from either therapy regimen. The authors concluded that these findings do not support the concept of a substantial benefit of PDL treatment in acne vulgaris.

Rosacea is a chronic inflammatory disorder involving especially the skin of the nose, forehead and cheeks that is characterized by congestion, flushing, telangiectasia (abnormal dilation of superficial blood vessels) and marked nodular swelling of tissues, especially of the nose. Goldberg (2005) stated that pharmacological agents remain the mainstay for initial and maintenance treatment of rosacea. However, monochromatic (i.e., laser) and polychromatic light-based therapies are increasingly being used for the treatment of certain signs of rosacea. The author noted that despite the increased use of lasers and other light-based therapies, few well-controlled studies have been conducted on their use for the treatment of rosacea. Furthermore, a Cochrane review on interventions for rosacea (van Zuuren et al, 2005) concluded that the quality of studies evaluating rosacea treatments was generally poor. The assessment found that there is evidence that topical
metronidazole and azelaic acid are effective (van Zuuren et al, 2005). The assessment found some evidence that oral metronidazole and tetracycline are effective. The assessment stated that there is insufficient evidence concerning the effectiveness of other treatments. The assessment concluded that good randomized controlled trials looking at these treatments are urgently needed.

Maw (2004) stated that a variety of treatment options are available for the treatment of genital warts; but few have been assessed in large-scale, randomized, placebo-controlled trials. Provider-applied surgical and non-surgical treatments have traditionally been the therapies of choice. Surgical therapies, including cryotherapy, electrotherapy, laser surgery and surgical excision, are generally equivalent in terms of wart clearance rates, but are associated with high rates of wart recurrence. Trichloroacetic acid is a widely used non-surgical therapy, but little is known about its efficacy, and it is associated with unpleasant side-effects. The patient-applied treatments imiquimod and podophyllotoxin are newer therapy choices which are more acceptable to both patients and practitioners. The wart clearance rates for these 2 treatments are similar, although imiquimod is associated with lower recurrence rates. In the face of increasing pressures on genitourinary clinic services, patient-applied home therapy represents an attractive option for the treatment of genital warts.

O'Mahony (2005) noted that commonly used physical treatment methods for genital warts include cryotherapy, trichloroacetic acid, laser, and electrocautery. However, many patients respond extremely well to home therapies with either podophyllotoxin or imiquimod. Patients prefer the comfort and dignity of home treatment, and this should be the first-line of treatment for the majority of patients. A routine screen for sexually transmitted infections is appropriate in most cases. Detailed explanation and reassurance are of paramount importance in reducing the psychological distress associated with this unpleasant genital condition.
Komericki et al (2006) stated that flashlamp-pumped PDL (FPDL) represents one of many treatment options for the management of viral warts (verrucae vulgaris), its effectiveness being comparable with that of conventional therapies. These researchers evaluated the effectiveness of FPDL light for the treatment of genital warts \( (n = 22) \). All patients showed complete remission after 1.59 (1 to 5) laser sessions and no scarring was observed. The authors concluded that the findings of this study demonstrate that FPDL is a simple and safe, cost- and time-saving alternative treatment option for genital warts and should be listed in genital warts treatment guidelines. Ockenfels and Hammes (2008) explained that FPDL had advantages over carbon dioxide laser in that the former is a nonablative approach to treatment of genital warts that appears to be associated with fewer side effects than the latter.

Scheinfeld and Lehman (2006) stated that genital human papillomavirus (HPV) infection is the most common sexually transmitted disease. Each year 1 million new cases of genital warts are diagnosed, 2/3 of which are in women. The estimated prevalence rate in the U.S. population is 15%. Human papillomavirus infects keratinocytes. Such infection can manifest clinically as warts. Treatment options for genital warts are numerous, well-established, and effective. Topical treatments include podophyllin resin, imiquimod, trichloroacetic acid, and podophyllotoxin. Surgical or destructive therapies include carbon dioxide laser, surgical excision, loop excision, cryotherapy, and electrodessication. Interferon can be injected locally or administered systemically to treat genital warts. Evidence of efficacy in the treatment of genital warts is drawn from randomized blind-controlled trials, prospective studies, and retrospective cohort studies. Evidence of efficacy appears to be good, but more head-to-head studies and comparisons of combination therapies versus monotherapy need to be done. Treatment of choice depends on the number, size, and location of lesions. There is little certainty that any approach is more effective than another, however costs differ. It would seem that the first line destructive treatment is cryotherapy, but surgery and electro-desiccation are more
effective. The first line topical treatments appear to be podophyllotoxin and imiquimod. Interferon is too expensive and trichloroacetic acid is too inconsistent to be recommended as primary treatment. It is unclear if combinations of therapies are more effective than monotherapy. Side effect profile, cost, effectiveness and convenience (ability to attend physician's office or to undertake protracted home treatment) define the choice of therapy.

Granuloma faciale (GF) is a rare, chronic benign vasculitis of unknown origin with characteristic clinicopathological features. It generally affects the skin of the face. Numerous medical and surgical treatments have been used with varying degrees of success. Several single-patient case reports have demonstrated the successful use of the pulsed dye laser in treating GF. Chatrath and Rohrer (2002) used long-pulsed tunable dye laser for the treatment of GF to target the vessels and minimize scarring. Confirmation of the diagnosis by a punch biopsy of the lesion was followed by 3 treatments on separate occasions 6 weeks apart with the long-pulsed tunable dye laser. There was significant flattening of the lesions after 2 treatments, with complete clearing after the 3rd. No scarring was detectable and there was no recurrence in the 9-month follow-up. The authors concluded that GF may be successfully treated with the long-pulsed tunable dye laser with minimal risk of scarring, especially in cosmetically sensitive areas.

Cheung and Lanigan (2005) evaluated the results of 4 patients with facial GF from one dermatological laser center that were treated with the Candela Vbeam PDL at 595 nm. Resolution of the GF was achieved in 2 of the 4 patients (50 %). This study provided further evidence that the PDL can help some patients with GF. Thus, it is still a valuable treatment option for GF, especially as it is safe, well-tolerated and quick. Furthermore, Wiederkehr and Schwartz (2008) stated that PDL is the preferred treatment for GF.

Cooper and Burge (2003) noted that Darier's disease (also known as Darier-White disease or keratosis follicularis) is a rare
cutaneous disease with an autosomal dominant mode of inheritance. Greasy papules and plaques arise on the seborrheic areas and in the flexures and almost all patients have nail abnormalities. Acantholysis and dyskeratosis are the typical histological findings. The underlying defect is a result of mutations in the ATP2A2 gene on chromosome 12q23-24 that encodes for a sarco/endoplasmic reticulum calcium ATPase (SERCA 2). Acantholysis is thought to result from desmosome breakdown. Darier's disease is an example of a dominantly inherited disease caused by haplo-insufficiency. Oral retinoids are the most effective treatment, but their adverse effects are troublesome. Topical retinoids, topical corticosteroids, surgery, and laser surgery have their advocates, but evidence for their effectiveness is sparse.

Schmitt and colleagues (2009) stated that Darier disease is often associated with pruritus and an unpleasant odor, causing medical and emotional problems. Ablative laser therapy has proven effective in ameliorating these symptoms. Side effects of this approach include permanent hypo-pigmentation and a risk of scarring. These investigators presented 2 cases where non-ablative therapy with pulsed dye lasers proved a safe and effective way to manage the intertriginous lesions. Although the mechanism of action is unclear, the success in this small case series study indicates that PDL therapy is an option in Darier disease. The authors concluded that larger numbers of patients, ideally in multi-center studies, must be treated in this way to confirm the results of this study.

In a preliminary study, Mortensen and colleagues (2008) evaluated the use of the PDL in the management of patients with established vocal fold scar. This was an Institutional Review Board-approved prospective study involving 11 patients. The causes of scarring were phonosurgery (n = 7), radiation (n = 2), and partial laryngectomy (n = 2). The subjects were evaluated pre- and post-procedure using the voice handicap index (VHI), laryngeal stroboscopy rating, voice recordings with acoustic and aerodynamic analysis, and self-evaluation. The PDL was applied with the fiberoptic
delivery system by 3 treatments at 1-month intervals in the office setting. Each treatment end-point was blanching of the treatment site. There were 3 women and 8 men in the study group. Ten of 11 patients subjectively improved by self-rating. No patients were worse; VHI improved from 48.44 pre-treatment to 35.55 at 6 months post-treatment (p < 0.05). The jitter at 6 months improved from 2.2 % to 1.7 % (p = NS) and shimmer improved from 3.7 % to 3.2 % (p = NS). The noise to harmonic ratio improved from 0.143 to 0.132 (p = NS). The mean phonotory flow went from 0.177 to 0.254 L/S (p < 0.05). Three raters blinded to treatment sequence rated the post-treatment stroboscopy findings as better than pre-treatment in a forced choice comparison, kappa score 0.903. The authors concluded that PDL is a safe and potentially promising treatment for established vocal fold scar.

Subjectively, no patients were worse and 10 of 11 patients reported improved voice. There was improvement in the VHI, acoustic measures of shimmer and jitter, and stroboscopy findings. They stated that further study using this approach in a larger cohort seems to be warranted.

Bernstein and co-workers (2011) noted that due to the hemoglobin-selective wavelength of the 595-nm PDL, it is a device of choice for treating cutaneous vascular lesions. However, it is less effective and removing dyschromia, which along with hyper-vascularity is a cardinal sign of cutaneous photodamage. A novel 607-nm dye laser was developed as a first step in creating a dual-wavelength PDL. A total of 25 subjects with dyschromia on the chest due to chronic photodamage were enrolled into an open-label study to explore the safety and efficacy of a 607-nm PDL. A total of 22 completing the study. Two treatments were administered to the chest, 1 month apart, with fluences ranging from 3 to 6 J/cm2 using a 10-mm diameter spot and pulse duration of 1.5 msec. Cross-polarized digital photographs were taken before and 2 months following the final treatment and rated for improvement by physicians in a blinded fashion. Improvement was rated on a 5-point scale with no subjects rated as poor (less than 25 %) clearance, 3 subjects (13.6 %) demonstrating fair (26 to 50 %)
improvement, 7 subjects (31.8 \%) rated as good (51 to 75 \%) improvement, 12 (54.5 \%) were rated as excellent (76 to 95 \%) improvement, while none was rated as outstanding improvement (greater than 95 \%). The authors concluded that this is the first study of the 607-nm PDL that showed it to be safe and effective for treating dyschromia of the chest due to chronic photodamage, and may in the future expand the ability of the PDL to treat photodamaged skin.

Onychomycosis is a common fungal condition of the fingernails or toenails which can be present for years without symptoms. The nail may become thicker and change to a yellowish-brown color. Hochman et al (2010) evaluated the treatment of onychomycosis using a novel 0.65-millisecond (ms) pulsed 1,064-nm laser. A total of 8 subjects were treated over 2 to 3 sessions spaced at least 3 weeks apart. Of the 8 subjects evaluated, 7 had negative post-treatment cultures after the 2nd or 3rd session. Treatments were well-tolerated by all subjects. These data suggested that treatment of onychomycosis with a 0.65-ms pulsed neodymium yttrium aluminum garnet (Nd:YAG) 1,064-nm laser should be studied further to determine the long-term clinical and microbiologic effect. The optimal number of treatment sessions for each patient needs to be determined.

Xanthelasma palpebrarum (XP), also known as xanthelasma, is often classified as a subtype of xanthoma. It is a sharply demarcated yellowish subcutaneous deposit of cholesterol, usually on or around the eyelids. Xanthelasma is common among individuals of Asian descent and those from the Mediterranean region. Because of the hereditary component, XP may or may not indicate high blood levels of cholesterol. Where there is no family history of XP, they usually indicate high cholesterol and may correlate with a risk of atheromatous disease. Although not harmful or painful, XP may be disfiguring and can be removed.

Karsai and colleagues (2010) noted that several studies have reported positive results of non-ablative laser treatment of XP,
but the published evidence is weak and inconclusive. These researchers evaluated the effect of PDL for the treatment of XP. A total of 20 female Caucasian patients with 38 lesions (less than or equal to 1 mm above skin level) were enrolled in this study. They received up to 5 treatment sessions with a PDL (wavelength, 585 nm; energy fluence, 7 J/cm²; pulse duration, 0.5 ms; spot size, 10 mm; number of passes, 2) at 2- to 3-week intervals. Photographs were taken before each treatment session and 4 weeks after the last treatment. Two independent examiners categorized clearance into 4 groups (no clearance [less than 25 % xanthelasma area(s) cleared], moderate [25 to 50 %], good [51 to 75 %], and excellent [greater than 75 %]). Patient satisfaction was assessed on a verbal rating scale. Approximately 2/3 of the lesions showed clearance greater than 50 %, and 1/4 had clearance greater than 75 %. Inter-rater reliability was excellent (contingency coefficient greater than 1.7 at all visits). Treatments were well-tolerated and had no major side effects. Patient satisfaction was generally high. The authors concluded that PDL is a promising approach for treating XP, especially when multiple sessions are performed. These findings need to be validated by well-designed studies.

Minars et al (2012) stated that basal cell carcinoma (BCC) is the most prevalent skin cancer. Because of its highly vascular characteristic, it is amendable to treatment with PDL (595nm). These researchers examined the safety and effectiveness of PDL for mostly facial BCCs. A total of 29 patients (16 men and 13 women) with 39 biopsy-proven BCCs were treated with 1 to 4 PDL therapies at 2- to 4-week intervals. The treatment parameters included pulse energy of 15 J/cm², pulse-length of 3 ms; with no dynamic cooling, and 7-mm spot size. The age of the patients was 30 to 90 years (mean of 73 years). Response rates were evaluated by the clinical assessments with mean follow-up of 11 months. Twenty-four patients with 32 tumors reached at least 3 months follow-up: 24/32 (75 %) tumors with complete resolution (mean 3 treatment sessions); 5/32 (16 %) tumors recurred; 3/32 (9 %) tumors with incomplete responses after 4 treatments. Minimal side effects and discomfort were experienced by the patients with PDL therapy. The authors
concluded that PDL is a safe, tolerable, and moderately effective method of treating various BCCs. Moreover, they stated that the ideal niche and standardized settings for PDL treatment of BCCs are yet to be determined.

Jalian et al (2014) examined the effect of repeated treatment with a combined 585-nm PDL and 1,064-nm Nd:YAG laser on BCCs of superficial and nodular subtypes of varying diameters. A total of 10 subjects with 13 biopsy-proven BCCs received 4 combined PDL and Nd:YAG at treatments 2 to 4 week intervals. None of the BCCs met the criteria for Mohs micrographic surgery. The tumor and 4 mm of peripheral skin were treated using standardized parameters delivered with a 7-mm spot with 10% overlap. The treated area was excised and evaluated histologically for residual tumor. The primary study end-point was histologic clearance of tumor. The secondary study end-point was blinded investigator assessment of clinical end-point and adverse effects. Approximately 50% of all tumors showed a complete response to 4 combined PDL and Nd:YAG treatments (n = 7/12, 58%). When stratified by size, 75% of all tumors less than 1 cm in diameter (n = 6/8) showed complete response. Tumor histologic types among the complete responders included superficial and nodular BCCs. All subjects with incompletely responding BCCs were on various forms of anti-coagulation, which these researchers hypothesized, may inhibit laser-mediated thrombosis necessary for the clinical effect. Blinded investigator assessment suggested that biopsy related erythema improves with subsequent laser treatments. The authors concluded that combined PDL and Nd:YAG laser is an effective means of reducing tumor burden in patients with BCC and may be a promising, emerging alternative therapy. Factors influencing treatment response includes the concomitant use of anti-coagulation. Moreover, they stated that further studies are needed to investigate and optimize the utility of this treatment protocol.

An UpToDate review on “Treatment and prognosis of basal cell carcinoma” (Chartier and Aasi, 2014) states that “Approaches to
enhance the efficacy of PDT have included administering multiple treatment sessions; combining ALA with dimethylsulfoxide (DMSO, a drug penetration enhancer), hyperthermia, or deferoxamine; extending the ALA application time; applying the photosensitizer with an occlusive dressing; combining ALA with curettage of the lesion or carbon dioxide laser; and administering ALA by intralesional rather than topical application. None of these approaches has an established role in the treatment of BCCs”. The review does not mention PDL as a therapeutic option. Furthermore, the National Comprehensive Cancer Network’s clinical practice guideline on “Basal cell and squamous cell skin cancers” (Version 2.2014) does not mention PDL as a therapeutic option.

Park et al (2014) evaluated vocal cord mucosectomy using PDL for its ability to completely remove lesions without deterioration of vocal quality in cases of vocal cord leukoplakia. To confirm the validity of a PDL, these researchers retrospectively analyzed the treatment outcomes of patients who received surgery preceded by PDL and compared these with the outcomes of patients who received vocal cord mucosectomy using carbon dioxide (CO2) laser. Between February 2007 and June 2012, a total of 36 patients were enrolled -- 17 received vocal cord treatment with a CO2 laser and 19 received operation with a PDL. To evaluate voice status, acoustic wave form analysis and electro-glottography were done, and voice handicap index was measured before and after the operation. The entire lesion was removed in all patients. Compared to pre-operative vocal parameters, the post-operative values for jitter were only improved in the PDL group. On stroboscopic findings, a diminution or lack of mucosal wave was observed in more CO2 laser cases than PDL cases. Significant improvement in voice handicap index results was only observed in the PDL group. The authors concluded that although long-term results with more patients are needed to establish the validity of PDL, this study confirmed the merits of PDL for the en-bloc removal of vocal cord leukoplakia and improved voice outcome.
Furthermore, an UpToDate review on “Oral lesions” (Goldstein and Goldstein, 2015) states that “There is no curative treatment for OPVL [oral proliferative verrucous leukoplakia]. Multiple therapies have been tried for temporary control of the disease, including surgical excision, CO2 and Nd:YAG laser ablation, cryotherapy, radiation therapy, photodynamic therapy, topical bleomycin, and oral retinoids. Recurrence rates of up to 90% have been reported for all treatment modalities”. This review does not mention PDL as a therapeutic option.

In a systematic review, Kotsakis et al (2014) addressed the following question: Is laser therapy, as a monotherapy or as an adjunctive therapy, an effective treatment modality for patients with peri-implantitis? The PubMed database of the U.S. National Library of Medicine and the Cochrane Central Register of Controlled Trials were electronically searched, complemented by manual searches up to June 2013. The search yielded 137 titles and abstracts. After initial screening, 15 of 137 publications were scrutinized during the second phase of the review. In the second phase, 9 articles were excluded from the analysis and 6 controlled, clinical studies were selected. Narrative synthesis of the results revealed that non-surgical laser treatment with a single application of either an erbium:yttrium-aluminum-garnet (Er:YAG) (2,940-nm) laser or a diode (660-nm) laser in combination with a phenothiazine chloride dye is efficient in controlling inflammation around treated implants for at least 6 months following intervention, whereas it has only a mild effect on reduction in probing depth (PD) and gain in clinical attachment level (CAL). There is limited information regarding the clinical application of the CO2 laser (10.6-μm) in the surgical treatment of peri-implantitis; however, its use may be promising. A meta-analysis could be performed only for the effectiveness of Er:YAG laser due to the heterogeneity of the studies and the limited amount of data available. Meta-analysis did not reveal statistically significant evidence for treatment effects in reducing PD and CAL levels in comparison to controls. The authors concluded that based on the limited information currently available, any superiority of laser treatment in comparison to conventional treatment of
peri-implantitis could not be identified. Considering the high heterogeneity and the low number of included studies, the authors concluded that non-surgical laser therapy may be investigated as phase I therapy for the treatment of peri-implantitis. They stated that future research should emphasize detailed description of the specific laser characteristics and power settings in clinical studies.

Natto et al (2015) evaluated the effectiveness of various types of lasers (neodymium-doped yttrium-aluminum-garnet [Nd:YAG], CO2, diode, erbium/chromium-doped yttrium-scandium-gallium-garnet [Er,Cr:YSGG], and erbium-doped yttrium-aluminum-garnet [Er:YAG]) in the treatment of peri-implantitis and their use in surgical and non-surgical procedures. Human studies for the treatment of peri-implantitis with laser therapy, published between 2002 and January 2014, were collected utilizing the electronic databases PubMed, Ovid, MEDLINE, Cochrane, and Google Scholar. Two reviewers conducted the study selection, data collection, and validity assessment. A total of 812 studies were selected in the initial title search; 13 studies were then chosen for this review. No human studies evaluated the effect of the Nd:YAG laser on peri-implantitis. The CO2 laser is reported to be safe and able to enhance bone regeneration. The diode laser (980-nm) seems to be effective in its bactericidal effect without changing the implant surface pattern. The Er,Cr:YSGG laser was reported to obtain bone regeneration around a failing implant in 1 case, while the Er:YAG laser exhibited a strong bactericidal effect against peri-odontopathic bacteria at a low energy level. The authors concluded that although lasers have shown promising results in reducing clinical signs of peri-implantitis, because of the limited sample sizes and short follow-up periods, no firm conclusion can be drawn at this moment. They stated that there is a need for well-designed, longitudinal, randomized controlled clinical trials.

Slaoui et al (2015) stated that cutaneous leishmaniasis caused by Leishmania tropica can leave troublesome and unsightly lesions. Treatment of these scars remains difficult. Pulsed-dye
laser is one therapeutic approach that may improve the clinical appearance of erythematous lesions. These researchers evaluated the effectiveness of PDL on the residual red lesions of erythematous facial leishmaniasis in 3 patients. Case 1: a 14-year old girl presented an ulcerative and erythematous nodular lesion on her left cheek. One month after treatment, an erythematous lesion measuring 3 cm persisted on the patient's cheek, without atrophy or hyper-pigmentation. Pulsed dye laser (595-nm) was used at the following settings: duration: 3 ms; spot size: 7 mm; energy: 8 J/cm(2). Case 2: a 43-year old woman presented an erythematous papular lesion on her right cheek. Following treatment, a 4-cm hypertrophic, red telangiectastic lesion remained. Pulsed dye laser was used with the following settings: pulse duration: 3 ms; spot-size: 10 mm; energy: 8 J/cm(2). Case 3: a 60-year old woman presented an erythematous papular lesion on her cheek. After treatment, an infiltrated erythematous macule with surface telangiectasia measuring 3.5 cm remained. Pulsed dye laser was also given using the following settings: pulse duration: 3 ms; spot size: 10 mm; energy: 8 J/cm(2). All 3 patients underwent 3 sessions of PDL. The erythematous and telangiectasic lesions showed improvement after the initial session and had completely disappeared after the 3rd session. Post-laser purpura subsided within around 10 days. Therapeutic response was assessed clinically by comparing photographs taken before and after treatment and follow-up lasted 12 months. The authors concluded that a number of treatments are available for red residual lesions but thanks to its effect on erythematous and vascular lesions, PDL has been shown to provide the most reproducibly good results and is the laser method of choice for this type of scar. A recent study of the dermoscopic features of DL identified the presence of vascular patterns in 100 % of cases in this infection, which may account for the efficacy of PDL. The use of PDL resulted in selective thermolysis that destroys small vessels. They stated that the findings of this study showed improvement with PDL regarding scar size, pliability, erythema and texture; further larger-scale studies could better determine the place of PDL in treating the sequelae of cutaneous leishmaniasis.
**Hailey-Hailey Disease:**

Hailey-Hailey disease, also known as familial benign pemphigus/benign familial pemphigus, is a hereditary (autosomal-dominant) acantholytic disorder affecting the intertriginous areas of the body. Available evidence for the use of PDL for this condition is limited to case reports.

Falto-Aizpurua and colleagues (2015) noted that benign familial chronic pemphigus, or HHD, is a recurrent bullous dermatitis that tends to have a chronic course with frequent relapses. Long-term treatment options include surgery with skin grafting or dermabrasion. Both are highly invasive and carry significant risks and complications. More recently, 'laser-abrasion' has been described as a less invasive option with a better side-effect profile. These investigators systematically reviewed the safety and effectiveness of CO2 laser therapy as a long-term treatment option for HHD, as well as provided a review of other lasers that have been reported with this goal. A total of 23 patients who had been treated with a CO2 laser were identified. After treatment, 10 patients (43 %) had had no recurrence, 10 (43 %) had greater than 50 % improvement, 2 (8 %) had less than 50 % improvement and 1 (4 %) patient had no improvement at all (follow-up period ranged from 4 to 144 months). Laser parameter variability was wide and adverse effects were minimal, including dyspigmentation and scarring. The authors concluded that reviewed evidence indicated this therapy offers a safe, effective treatment alternative for HHD with minimal risk of side-effects. Moreover, they stated that larger, well-designed studies are necessary to determine the optimal treatment parameters.

**Cutaneous Amyloidosis:**

Al Yahya (2016) noted that primary cutaneous amyloidosis (PCA) is a condition characterized by tissue deposition of misfolded proteins; it can present in different forms (e.g., macular, lichen, and nodular amyloidosis). These lesions can be of cosmetic concern and are difficult to treat. Many therapeutic
modalities have been suggested for the treatment of PCA, with variable efficacy, including topical and systemic medications, phototherapy, electro-dessication, dermabrasion, cryosurgery, and lasers. Over the past 10 years, several studies have reported successful treatment of PCA with different types of lasers; however, a review of these studies has never been reported in the dermatologic literature. These investigators reviewed the safety and effectiveness of lasers in the treatment of PCA. A search of the National Library of Medicine's PubMed Database was performed. Studies were considered for inclusion based on their relevance, and specific data were extracted from all included studies. A total of 11 studies, comprising 64 patients, were included in this review. Significant improvements were observed in macular and lichen amyloidosis patients treated with CO2 laser in 2 studies, while a number of case series and case reports showed good results with other types of laser in the treatment of PCA. The authors concluded that this review was limited by the lack of large double-blinded randomized controlled trials (RCTs) and the overall small sample size. They stated that laser treatment is a promising option in the treatment of PCA; and future RCTs are needed to compare the effectiveness of different types of lasers and to select the best parameters for different types of PCA.

Granuloma Annulare:

Verne and associates (2016) stated that granuloma annulare (GA) is a benign asymptomatic dermatosis that typically manifests in papules arrayed in annular arrangements. Many methods of treatment have been used with variable degrees of success, but finding a consistent and long-term treatment has proven a challenge. These investigators evaluated the latest published research on the use of lasers in the treatment of GA. A systematic search of the National Library of Medicine's PubMed database was performed to identify relevant articles; 7 reports met the inclusion criteria for the review. Evidence for the use of PDL, fractional photo-thermolysis, and Excimer laser in the treatment of GA was found. However, findings were limited by a lack of well-designed clinical trials objectively
evaluating the use of lasers in the treatment of GA. The literature review found a number of case reports and case series that reported successful outcomes of the use of lasers in the treatment of GA. The authors concluded that the promising results reported in the literature, coupled with the lack of a well-designed review on this topic, reflect the importance of the need for larger and better-designed studies on the use of lasers to treat GA.

Infantile Hemangiomas:

Shen and co-workers (2015) noted that infantile hemangiomas (IH) are common pediatric tumors. This meta-analysis was performed to review the safety and effectiveness of PDL in the treatment of IH. A total of 7 databases were searched, including PubMed, OvidSP, Karger, Elsevier, EMBASE, Web of Science and Wiley Online Library. The review collected the characteristics of year of publication, hemangiomas cases, prior treatment, laser parameters, adverse side, pre-treatment symptom, and number of response from all articles. A total of 1,580 studies were identified, the first round search retrieved 39 articles that met inclusion criteria. Of those, only 13 articles with 1,529 hemangiomas were included in the meta-analysis. This meta-analysis demonstrated an overall resolution rate of 89.1 % with 6.28 % incidence of adverse effect. The authors concluded that PDL may be the effective modality to decrease the proliferative phase and accelerate rates of involution and resolution with few adverse events.

<table>
<thead>
<tr>
<th>CPT Codes / HCPCS Codes / ICD-10 Codes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Information in the [brackets] below has been added for clarification purposes. Codes requiring a 7th character are represented by &quot;*&quot;:</td>
</tr>
<tr>
<td>Verruca warts and pyogenic granuloma:</td>
</tr>
<tr>
<td>CPT codes covered if selection criteria are met:</td>
</tr>
<tr>
<td>Code</td>
</tr>
<tr>
<td>--------</td>
</tr>
<tr>
<td>17110</td>
</tr>
<tr>
<td>17111</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

- **B08.1** Molluscum contagiosum
- **B07.0 - B07.9** Viral warts [verruca]
- **B08.1** Molluscum contagiosum
- **L98.0** Pyogenic granuloma [face and neck]

**Port wine stains, other hemangiomas, and glomangiomas:**

**CPT codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17106</td>
<td>Destruction of cutaneous vascular proliferative lesions (e.g., laser techniques); less than 10 sq cm</td>
</tr>
<tr>
<td>17107</td>
<td>10.0 to 50.0 sq cm</td>
</tr>
<tr>
<td>17108</td>
<td>over 50.0 sq cm</td>
</tr>
</tbody>
</table>

**ICD-10 codes covered if selection criteria are met:**

- **D18.01** Hemangioma of skin and subcutaneous tissue [face and neck]
- **Q82.5** Congenital non-neoplastic nevus (e.g., Port-wine stain, strawberry nevus and birthmarks) [face and neck]

**Benign lesions:**

**CPT codes covered if selection criteria are met:**

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17110</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions</td>
</tr>
<tr>
<td>17111</td>
<td>15 or more lesions</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

- **B55.1** Cutaneous leishmaniasis
Pre-malignant lesions:

CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17000</td>
<td>Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemo surgery, surgical curettement), premalignant lesions (eg, actinic keratoses); first lesion</td>
</tr>
<tr>
<td>17003</td>
<td>second through 14 lesions, each (List separately in addition to code for first lesion)</td>
</tr>
<tr>
<td>17004</td>
<td>15 or more lesions</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>K13.21</td>
<td>Leukoplakia of oral mucosa, including tongue</td>
</tr>
</tbody>
</table>

Plaque psoriasis:

CPT codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>96920</td>
<td>Laser treatment for inflammatory skin disease (psoriasis); total area less than 250 sq cm</td>
</tr>
<tr>
<td>96921</td>
<td>250 sq cm to 500 sq cm</td>
</tr>
<tr>
<td>96922</td>
<td>over 500 sq cm</td>
</tr>
</tbody>
</table>

ICD-10 codes covered if selection criteria are met:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>L40.0</td>
<td>Psoriasis vulgaris [plaque]</td>
</tr>
</tbody>
</table>

ICD-10 codes not covered for indications listed in the CPB (not all-inclusive):

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>B08.1</td>
<td>Molluscum contagiosum</td>
</tr>
<tr>
<td>B35.1</td>
<td>Tinea unguium [onychomycosis]</td>
</tr>
<tr>
<td>D18.1</td>
<td>Lymphangioma, any site</td>
</tr>
<tr>
<td>D22.70</td>
<td>Benign neoplasm of skin of lower limb, including hip [angiokeratoma]</td>
</tr>
<tr>
<td>D22.72</td>
<td></td>
</tr>
<tr>
<td>D23.70</td>
<td></td>
</tr>
<tr>
<td>D23.72</td>
<td></td>
</tr>
<tr>
<td>H02.60</td>
<td>Xanthelasma [palpebrum]</td>
</tr>
<tr>
<td>H02.66</td>
<td></td>
</tr>
</tbody>
</table>
### CPT codes covered for indications listed in the CPB:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>17260</td>
<td>Destruction, malignant lesion (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), trunk, arms or legs; lesion diameter 0.5 cm or less</td>
</tr>
<tr>
<td>17261</td>
<td>lesion diameter 0.6 to 1.0 cm</td>
</tr>
<tr>
<td>17262</td>
<td>lesion diameter 1.1 to 2.0 cm</td>
</tr>
<tr>
<td>17263</td>
<td>lesion diameter 2.1 to 3.0 cm</td>
</tr>
<tr>
<td>17264</td>
<td>lesion diameter 3.1 to 4.0 cm</td>
</tr>
<tr>
<td>17266</td>
<td>lesion diameter over 4.0 cm</td>
</tr>
<tr>
<td>ICD-10 Code</td>
<td>Description</td>
</tr>
<tr>
<td>-------------</td>
<td>-------------</td>
</tr>
<tr>
<td>17270</td>
<td>Destruction, malignant lesion (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), scalp, neck, hands, feet, genitalia; lesion diameter 0.5 cm or less</td>
</tr>
<tr>
<td>17271</td>
<td>lesion diameter 0.6 to 1.0 cm</td>
</tr>
<tr>
<td>17272</td>
<td>lesion diameter 1.1 to 2.0 cm</td>
</tr>
<tr>
<td>17273</td>
<td>lesion diameter 2.1 to 3.0 cm</td>
</tr>
<tr>
<td>17274</td>
<td>lesion diameter 3.1 to 4.0 cm</td>
</tr>
<tr>
<td>17276</td>
<td>lesion diameter 0.5 cm or less</td>
</tr>
<tr>
<td>17280</td>
<td>Destruction, malignant lesion (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), face, ears, eyelids, nose, lips, mucous membrane; lesion diameter 0.5 cm or less</td>
</tr>
<tr>
<td>17281</td>
<td>lesion diameter 0.6 to 1.0 cm</td>
</tr>
<tr>
<td>17282</td>
<td>lesion diameter 1.1 to 2.0 cm</td>
</tr>
<tr>
<td>17283</td>
<td>lesion diameter 2.1 to 3.0 cm</td>
</tr>
<tr>
<td>17284</td>
<td>lesion diameter 3.1 to 4.0 cm</td>
</tr>
<tr>
<td>17286</td>
<td>lesion diameter 0.5 cm or less</td>
</tr>
</tbody>
</table>

**ICD-10 codes not covered for indications listed in the CPB:**

- C44.01
- C44.111 - C44.119
- C44.211 - C44.219
- C44.310 - C44.319
- C44.41
- C44.510 - C44.510
- C44.611 - C44.619
- C44.711 - C44.719
- C44.81
- C44.91

**Basal cell carcinoma of skin**
The above policy is based on the following references:

2003;362(9393):1342.
28(7):615-616.


35. Foerster V, Murtagh J, Fiander M. Pulsed dye laser therapy of port wine stains. Technology Report No. 78. Ottawa, ON: Canadian Agency for Drugs and Technologies in Health (CADTH); 2007.


62. Chartier TK, Aasi SZ. Treatment and prognosis of basal cell carcinoma. UpToDate Inc., Waltham, MA. Last reviewed April, 2014.


