UnitedHealthcare®

MEDICAL POLICY

LIGHT AND LASER THERAPY FOR CUTANEOUS LESIONS AND PILONIDAL DISEASE

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Related Policies:

- Cosmetic and Reconstructive Procedures
- Propranolol Treatment for Infantile Hemangiomas: Inpatient Protocol

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare benefit plans. When deciding coverage, the enrollee specific document must be referenced. The terms of an enrollee's document (e.g., Certificate of Coverage (COC) or Summary Plan Description (SPD) and Medicaid State Contracts) may differ greatly from the standard benefit plans upon which this Medical Policy is based. In the event of a conflict, the enrollee's specific benefit document supersedes this Medical Policy. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the enrollee specific plan benefit coverage prior to use of this Medical Policy. Other Policies and Coverage Determination Guidelines may apply. UnitedHealthcare reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

UnitedHealthcare may also use tools developed by third parties, such as the MCG™ Care Guidelines, to assist us in administering health benefits. The MCG™ Care Guidelines are intended to be used in connection with the independent professional medical judgment of a qualified health care provider and do not constitute the practice of medicine or medical advice.

BENEFIT CONSIDERATIONS

Several states mandate coverage for laser therapy for treatment of port-wine stains and cutaneous hemangiomata under certain circumstances. As in all benefit adjudication, federal and state legislated mandates must be followed. Therefore, the applicable state-specific requirements and the enrollee-specific benefit document must be reviewed to determine what benefits, if any, exist for laser therapy for treatment of port-wine stains and cutaneous hemangiomata.

Essential Health Benefits for Individual and Small Group:
For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs"). Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs. However, if such plans choose to provide coverage

for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans. The determination of which benefits constitute EHBs is made on a state by state basis. As such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage.

COVERAGE RATIONALE

Cutaneous Lesions

Pulsed dye laser therapy is proven and medically necessary for the treatment of port-wine stains and cutaneous hemangiomata.

Light and laser therapy including intense pulsed light are unproven and not medically necessary for the treatment of rosacea and rhinophyma.

The quantity and quality of the evidence is insufficient to recommend light and laser treatment for the treatment of rosacea and rhinophyma. The quality of evidence is limited. Additional research is needed to determine efficacy and safety and to clarify patient selection and treatment parameters.

Light and laser therapy including light phototherapy, photodynamic therapy, intense pulsed light, and pulsed dye laser are unproven and not medically necessary for treating active acne vulgaris.

There is insufficient evidence to recommend the use of light and laser therapy for the treatment acne vulgaris. Studies evaluating light and laser therapy for acne typically are short term, lack controls or the patient serves as their own control, have small sample sizes, and do not compare laser therapy with standard acne treatment. Well-designed studies are necessary to clarify the role of light and laser therapy for acne.

Pilonidal Sinus Disease

Laser hair removal is unproven and not medically necessary for the treatment of pilonidal sinus disease.

There is insufficient evidence to conclude that laser hair removal is effective for treating pilonidal sinus disease. Most of the studies regarding this treatment were small and uncontrolled. Additional well-designed controlled trials are needed to determine the efficacy of laser hair removal for pilonidal disease.

APPLICABLE CODES

The Current Procedural Terminology (CPT®) codes and Healthcare Common Procedure Coding System (HCPCS) codes listed in this policy are for reference purposes only. Listing of a service code in this policy does not imply that the service described by this code is a covered or non-covered health service. Coverage is determined by the enrollee specific benefit document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claims payment. Other policies and coverage determination guidelines may apply. This list of codes may not be all inclusive.

CPT® Code	Description
Cutaneous Vascular Lesion Procedure Codes	
17106	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); less than 10 sq cm
17107	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); 10.0 to 50.0 sq cm
17108	Destruction of cutaneous vascular proliferative lesions (eg, laser technique); over 50.0 sq cm

Laser Hair Removal	
17380	Electrolysis epilation, each 30 minutes

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ICD-9 Code	Description
Cutaneous Vascular Diagnosis Codes (Proven Diagnosis Codes)	
228.00	Hemangioma of unspecified site
228.01	Hemangioma of skin and subcutaneous tissue
448.0	Hereditary hemorrhagic telangiectasia
448.1	Nevus, non-neoplastic
757.32	Congenital vascular hamartomas
759.6	Other congenital hamartoses, not elsewhere classified
Pilonidal Disease Diagnosis Codes (Unproven Diagnosis Codes)	
685.0	Pilonidal cyst with abscess
685.1	Pilonidal cyst without mention of abscess
Rosacea Diagnosis Code (Unproven Diagnosis code)	
695.3	Rosacea
Acne Vulgaris (Unproven Diagnosis Code)	
706.1	Other acne

Coding Clarification: Viral warts or plantar warts are not considered to be vascular proliferative lesions. Therefore, laser therapy used to treat warts should not be reported with CPT codes 17106, 17107, or 17108.

ICD-10 Codes (Preview Draft)
In preparation for the transition from ICD-9 to ICD-10 medical coding on **October 1, 2015***, a sample listing of the ICD-10 CM and/or ICD-10 PCS codes associated with this policy has been provided below for your reference. This list of codes may not be all inclusive and will be updated to reflect any applicable revisions to the ICD-10 code set and/or clinical guidelines outlined in this policy. **The effective date for ICD-10 code set implementation is subject to change.*

ICD-10 Diagnosis Code (Effective 10/01/15)	Description
Cutaneous Vascular Diagnosis Codes (Proven Diagnosis Codes)	
D18.00	Hemangioma unspecified site
D18.01	Hemangioma of skin and subcutaneous tissue
I78.0	Hereditary hemorrhagic telangiectasia
I78.1	Nevus, non-neoplastic
Q82.5	Congenital non-neoplastic nevus
Q85.8	Other phakomatoses, not elsewhere classified
Q85.9	Phakomatosis, unspecified
Pilonidal Disease Diagnosis Codes (Unproven Diagnosis Codes)	
L05.01	Pilonidal cyst with abscess
L05.02	Pilonidal sinus with abscess
L05.91	Pilonidal cyst without abscess
L05.92	Pilonidal sinus without abscess
Rosacea Diagnosis Code (Unproven Diagnosis code)	
L71.0	Perioral dermatitis
L71.1	Rhinophyma
L71.8	Other rosacea
L71.9	Rosacea, unspecified
Acne Vulgaris (Unproven Diagnosis Codes)	
L70.0	Acne vulgaris

L70.1	Acne conglobata
L70.3	Acne tropica
L70.4	Infantile acne
L70.5	Acne excoriee des jeunes filles
L70.8	Other acne
L70.9	Acne, unspecified
L73.0	Acne keloid

DESCRIPTION OF SERVICES

Port-Wine Stains and Hemangiomata
Port wine stains (PWS) are a type of vascular lesion involving the superficial capillaries of the skin. At birth, the lesions typically appear as flat, faint, pink macules. With increasing age, they darken and become raised, red-to-purple nodules and papules in adults. Congenital hemangiomas are benign tumors of the vascular endothelium that appear at or shortly after birth. Hemangiomas are characterized by rapid proliferation in infancy and a period of slow involution that can last for several years. Complete regression occurs in approximately 50% of children by 5 years of age and 90% of children by 9 years of age (Hayes 2012).

Lasers are used to treat both PWS and hemangiomas. The flashlamp-pumped pulsed dye laser (PDL) was developed specifically for the treatment of cutaneous vascular lesions. It emits one specific color, or wavelength, of light that can be varied in its intensity and pulse duration. Cryogen spray cooled PDL (CPDL) involves the application of a cryogen spurt to the skin surface milliseconds prior to laser irradiation. This cools the epidermis without affecting the deeper PWS blood vessels, and reduces the thermal injury sustained by the skin during laser treatment. The goals of PDL therapy are to remove, lighten, reduce in size, or cause regression of the cutaneous vascular lesions in order to relieve symptoms and alleviate or prevent medical or psychological complications.

Rosacea and Rhinophyma
Rosacea is a chronic cutaneous disorder primarily affecting the central face, including the cheeks, chin, nose, and central forehead. It is often characterized by remissions and exacerbations. Based on current knowledge, rosacea is considered a syndrome or typology, and exhibits various combinations of cutaneous signs such as flushing, erythema, telangiectasia, edema, papules, pustules, ocular lesions, and rhinophyma. Monochromatic (i.e., laser) therapies are increasingly being considered for treatment of the signs and symptoms associated with rosacea, including the pulsed dye laser (PDL), high-energy 532 nm pulse potassium titanyl phosphate (KTP) laser, and a variety of intense pulsed light (IPL) sources.

Rhinophyma is a disfiguring condition of the external nose characterized by tissue hypertrophy, dilated follicles, and irregular nodular overgrowth. Although the etiology of rhinophyma remains unknown, it typically appears in the later stages of rosacea and forms gradually over years. A variety of surgical techniques including cryosurgery electrosurgery, dermabrasion, scalpel and razor blade excision, and laser surgery have been used to reduce visible blood vessels and remove rhinophymatous tissue.

Acne Vulgaris
Acne vulgaris is a common skin condition associated with obstruction and inflammation of the hair follicle and sebaceous glands. This may result in the formation of comedones, papules, pustules, nodules, and cysts. Light and laser therapies are being considered to treat acne. Light therapy is defined as exposure to nonionizing radiation for therapeutic benefit. It can include the use of phototherapy, intense pulsed light, and photodynamic therapy (PDT). Photodynamic therapy is the use of visible light in addition to a topical application of a photosensitizer, such as 5-aminolevulinic acid (ALA) or methyl aminolaevulinate (MAL). Laser types that are being studied to

treat acne include near-infrared laser, pulsed dye laser (PDL), long-PDL, argon laser, smooth beam laser, and diode laser.

Pilonidal Sinus Disease
Pilonidal sinus disease is a chronic infection in the skin that occurs slightly above the crease between the buttocks. It develops into a cyst called a pit or sinus. Hair may protrude from the pit, and several pits may be seen. Because the cause of pilonidal sinus disease has been attributed to hair follicle ingrowth, laser hair removal or laser epilation has been proposed as an adjunct or alternative to surgery.

CLINICAL EVIDENCE

Port-Wine Stains (PWS) and Hemangiomata
There is sufficient evidence to support the use of pulsed dye laser (PDL) therapy in patients with PWS who require definitive treatment to alleviate or prevent medical or psychological complications (Hayes Directory, Pulsed Dye Laser Therapy for Cutaneous Vascular Lesions, 2012). Results from the reviewed studies indicate that PDL therapy for PWS can produce a better blanching response with fewer side effects than either the copper vapor laser or the argon-pumped continuous-wave dye laser (Sheehan-Dare and Cotterill, 1994; Dover et al., 1995; Edstrom et al., 2002).

A Cochrane review (Faurschou et al, 2011) was conducted to evaluate participant satisfaction, clinical efficacy, and adverse effects of the treatment of port-wine stains by lasers and light sources. The review included five randomized clinical trials involving a total of 103 participants. The pulsed dye laser was evaluated in all five trials. The use of pulsed dye laser resulted in more than 25% reduction in redness. This was after 1 to 3 treatments for up to 4 to 6 months postoperatively in 50% to 100% of the participants. The authors concluded that pulsed dye laser leads to clinically relevant clearance of port-wine stains.

There is sufficient evidence of efficacy to support the use of PDL therapy for treatment of superficial hemangiomas or the superficial component of mixed hemangiomas, and for post-involutional hemangiomas and telangiectasia in infants or children requiring definitive treatment to alleviate or prevent medical or psychological complications. (Hayes Directory, Pulsed Dye Laser Therapy for Cutaneous Vascular Lesions, 2012). One reasonably well-designed randomized controlled trial evaluating the efficacy of 585 nm PDL in infants found that early PDL treatment of uncomplicated hemangiomas was no better than a wait-and-see policy, and may even increase the risk of skin atrophy and hypopigmentation (Batta et al., 2002). In contrast, evidence from lesser quality studies suggests that PDL therapy can induce involution, prevent enlargement, or eliminate cutaneous hemangiomas in selected cases (Chang et al., 2001; Raulin and Greve, 2001; Hohenleutner et al., 2001). None of the deep hemangiomas or the deep components of mixed hemangiomas responded to PDL therapy. The results from randomized controlled trials suggest that the hemangiomas that responded well in other studies may have resolved spontaneously without treatment, thereby obviating the need for putting an infant at risk of such adverse effects as pain, scarring, and skin pigment changes. However, this is balanced by the consideration that between 20% and 40% of children are left with residual skin changes, ranging from mild telangiectasia to permanent deformation of facial features, after spontaneous involution of hemangiomas (Hohenleutner and Landthaler, 2002).

Faurschou et al. (2009) compared the efficacy and adverse events of pulsed dye laser (PDL) and broadband intense pulsed light (IPL) in a randomized clinical trial that included 20 patients with port-wine stains (PWS). Both PDL and IPL lightened PWS. Median clinical improvements were significantly better for PDL (65%) than IPL (30%). A higher proportion of patients obtained good or excellent clearance rates with the PDL (75%) compared with IPL (30%). Skin reflectance also documented better results after PDL (33% lightening) than IPL (12% lightening).

Remlova et al. (2011) evaluated hemangioma treatment using four different types of lasers, namely, alexandrite, Er:YAG, CO(2), and pulsed dye laser (PDL). A group of 869 consecutive patients with hemangioma was retrospectively reviewed. The patients including in the study were divided into four groups according to the type of laser used: Alexandrite laser (n=85), CO(2) laser (n=78), Er:YAG laser (n=105), and PDL laser (n=601). All patients were treated in one session. The ablative systems vaporized the tissues until the hemangioma was removed. The non-ablative systems used one shot, which destroyed the hemangioma blood vessels. For the treatment efficacy analysis, the following factors were evaluated: therapeutic effect (yes vs. no), loss of pigment (yes vs. no), and appearance of scar (yes vs. no). From results it was evident that the therapeutic effect of all the lasers except alexandrite was very high; almost 100%. In the CO(2) and the Er:YAG laser groups a high percentage of side effects was also observed. Exposure to these lasers caused loss of pigment and scar formation in many cases. According to the authors, the best therapeutic effect, with only minor side effects, was achieved with the PDL laser.

Acne Vulgaris

Erceg et al. (2013) systematically reviewed the literature concerning pulsed dye laser (PDL) treatment for inflammatory skin diseases including acne vulgaris. The authors concluded that PDL treatment can be recommended as an effective and safe treatment for acne vulgaris (recommendation grade B). The authors noted that despite the promising results found in studies, it is still unclear whether PDL treatment for acne will become a standard treatment in the future. The authors state that no large intra-patient, split-face comparative studies were done with PDL treatment in comparison with other well-established, easily accessible treatments, so the added value to conventional forms of therapy is still unclear.

Hamilton et al. (2009) conducted a systematic review of randomized controlled trials of light and laser therapies for acne vulgaris. The authors identified 25 trials (694 patients), 13 of light therapy and 12 of light therapy plus light-activated topical cream (photodynamic therapy, PDT). Overall, the results from trials of light alone were disappointing, but the trials of blue light, blue-red light and infrared radiation were more successful, particularly those using multiple treatments. Red-blue light was more effective than topical 5% benzoyl peroxide cream in the short term. Most trials of PDT showed some benefit, which was greater with multiple treatments, and better for noninflammatory acne lesions. However, the improvements in inflammatory acne lesions were not better than with topical 1% adapalene gel, and the side-effects of therapy were unacceptable to many participants. The authors concluded that some forms of light therapy were of short-term benefit. Patients may find it easier to comply with these treatments, despite the initial discomfort, because of their short duration. However, very few trials compared light therapy with conventional acne treatments, were conducted in patients with severe acne, or examined long-term benefits of treatment. According to the authors, further trials comparing light therapy with conventional treatment, using a bigger effect size in the power calculations, with correspondingly greater numbers of participants, would help to determine the usefulness of light therapy in treating acne.

Haerdersdal et al. (2008) reviewed 16 RCTs and three controlled trials (n=587) to assess the effects of optical treatments for acne vulgaris. The interventions included PDL, PDT, infrared lasers, broad-spectrum light sources and intense pulsed light. Most studies were intraindividual trials (12/19) with blinded response evaluations (12/19) and evaluated a short-term efficacy up to 12 weeks after treatment (17/19). Optical treatments were compared to standard intervention in two trials. Side-effects from optical treatments included pain, erythema, edema, crusting, hyperpigmentation, pustular eruptions and were reported to be more intense for treatments combined with ALA or MAL. It was summarized that based on the available evidence, optical treatments may improve inflammatory acne on a short-term basis. The most consistent outcomes were found for PDT. The reviewers noted that further studies are needed comparing optical versus conventional treatments.

Karsai et al. (2010) assessed the efficacy of adjuvant pulsed-dye laser (PDL) treatment when combined with a proven topical treatment [fixed-combination clindamycin 1%-benzoyl peroxide 5% hydrating gel (C/BPO)]. Eighty patients were randomized in a 1 : 2 ratio to receive C/BPO

alone or in combination with PDL treatment. Patients were evaluated at baseline and at 2 and 4 weeks after initial treatment. Both groups showed a significant improvement during observation, 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 their findings do not support the concept of a substantial benefit of PDL treatment in acne vulgaris.

Darné et al. (2011) assessed the clinical efficacy and long-term outcome of the 1450 nm laser for inflammatory acne vulgaris. A split-face format was used: the side of the face to be treated was randomized with the other side serving as a within-patient control. Treatment was delivered with the Candela 1450 nm Smoothbeam laser using a double-pass technique. Three treatments were performed monthly. Participants were followed up every 3 months for 12 months after the last treatment. The single assessor was blinded as to the side treated. Thirty-eight participants entered the study and 32 completed the study. Within participants, on average, the lesion count reduced by the same amount on both sides of the face. On average, acne grade reduced by the same amount on both sides. Twelve months after the last treatment (n = 23) the change in lesion count and grade between the treated and control sides of the face remained similar. The authors concluded that treatment with the 1450 nm laser does not reduce inflammatory lesion count or acne grade when compared with a control side in a split-face format study. The authors noted that both sides of the face improved and a systemic effect of the laser is possible.

El-Latif et al. (2013) compared the clinical efficacy of intense pulsed light therapy (IPL) versus benzoyl peroxide(BP) 5 % for the treatment of inflammatory acne. Fifty patients (15 males and 35 females) aged (18-27 years), with mild-to-severe acne and Fitzpatrick skin phototype IV were enrolled in the study. The patients were equally divided into two groups. The first group was treated by benzoyl peroxide while the second group was treated by IPL. Treatment with both benzoyl peroxide and IPL resulted in considerable improvement of the acne after 5 weeks of treatment. Comparing the effects of both therapies, BP produced better results than IPL. The difference in the results was statistically significant at the midpoint of the study. However, this difference was insignificant at the end of study.

Papageorgiou et al. (2000) evaluated the use of blue light and a mixed blue and red light in the treatment of acne vulgaris. One hundred and seven patients with mild to moderate acne vulgaris were randomized into four treatment groups: blue light, mixed blue and red light, cool white light and 5% benzoyl peroxide cream. Subjects in the phototherapy groups used portable light sources and irradiation was carried out daily for 15 min. Comparative assessment between the three light sources was made in an observer-blinded fashion, but this could not be achieved for the use of benzoyl peroxide. Assessments were performed every 4 weeks. After 12 weeks of active treatment a mean improvement of 76% in inflammatory lesions was achieved by the combined blue-red light phototherapy; this was significantly superior to that achieved by blue light (at weeks 4 and 8 but not week 12), benzoyl peroxide (at weeks 8 and 12) or white light (at each assessment). The final mean improvement in comedones by using blue-red light was 58% (95% confidence interval 45-71), again better than that achieved by the other active treatments used, although the differences did not reach significant levels. The authors concluded that phototherapy with mixed blue-red light is an effective means of treating acne vulgaris of mild to moderate severity, with no significant short-term adverse effects. Study limitations included limited follow-up period, mild to moderate acne was not defined, and lack of power analysis (sample size was too small).

Other available studies evaluating phototherapy for treating acne were limited by small sample sizes and short follow-up (Ammad et al. 2008; Morton et al. 2005; Gold et al. 2005).

Goldman and Boyce (2003) studied the effect of aminolevulinic acid (ALA) and Photodynamic therapy (PDT) in 22 patients with mild to moderate acne vulgaris of the face. Although not randomized, the patients were divided into 2 groups: (1) patients treated with blue light, once a week for 2 weeks; (2) patients treated with topical ALA and PDT for 2 treatments occurring 2

weeks apart. Patients treated with blue light only experienced a 25% improvement in acne severity, a 40% decrease in papules, a 65% decrease in pustules, and a 62% decrease in comedones. Patients treated with ALA and PDT experienced a 32% improvement in acne severity, 68% decrease in papules, 61% decrease in pustules, and 62% decrease in comedones. However, since this study had no control for blue light and was not randomized, the magnitude of the treatment effect is difficult to determine.

Several other randomized controlled trials that were small in size found that PDT may be effective in the treatment of acne vulgaris (Horfelt et al., 2006; Wiegell and Wulf, 2006; Alexiades-Armenakas, 2006).

The European Dermatology Forum issued European evidence-based guidelines for the treatment of acne that included the following recommendations:

- A recommendation for or against treatment of comedonal acne with visible light as monotherapy, lasers with visible wavelengths and lasers with infrared wavelengths, with intense pulsed light (IPL) and photodynamic therapy (PDT) cannot be made at the present time. Although there are some studies of the treatment of non-inflammatory lesions (NIL) with laser and light sources, the published evidence is still very scarce. A standardized treatment protocol and widespread clinical experience are still lacking.
- Due to a lack of sufficient evidence, it is currently not possible to make a recommendation for or against treatment with IPL and laser in severe papulopustular acne. Although PDT is effective in the treatment of severe papular pustular, moderate nodular acne, it cannot yet be recommended due to a lack of standard treatment regimens that ensure a favorable profile of acute adverse reaction.
- Due to lack of sufficient evidence, it is currently not possible to make a recommendation for or against treatment with IPL, or laser in conglobate acne.

These recommendations are based on available evidence and expert consensus (Nast et al. 2012).

European guidelines for topical photodynamic therapy indicate that there is no consensus on an optimal photodynamic protocol in acne (Morton et al. 2012).
The studies evaluating light and laser therapy for treating acne vulgaris are limited by small sample sizes, variability in patient selection criteria, and limited comparisons with standard therapies. There is insufficient evidence to support the use of light and laser therapy for the treatment of acne vulgaris.

Rosacea and Rhinophyma
In earlier relatively short-term studies, treatment with PDL and IPL generally resulted in varying degrees of improvement in rosacea symptoms, most notably reduction of facial telangiectases, flushing, and erythema, without producing sustained side effects (Clark et al., 2002; Taub, 2003; Lonne-Rahm et al., 2004; Tan et al., 2004; Schroeter et al., 2005; Uebelhoer et al., 2007). Clearance rates for flushing, skin texture, redness, and telangiectases ranged from 50% to 87%, depending on the treatment location on the face. Only one study, conducted by Clark et al. (2002), reported statistically significant reductions in erythema, flushing, and telangiectasia scores. Treatment of papules and pustules associated with rosacea was evaluated in only one study, and results indicated that 64% of patients noted fewer papules or pustules (Taub et al., 2003). Schroeter et al. (2005) reported more than 75% clearance of facial telangiectases, with clearance most notable on the forehead. The response was not correlated with any technical variables, such as pulse time, number of treatments, wavelength, or fluence. Lesion recurrence was observed in only 4 sites after 3 years following treatment. In the only randomized, blinded, comparative study, Uebelhoer et al. (2007) reported that the 532-nm KTP device was at least or more effective than the 595-nm PDL device. The KPL laser achieved 85% clearance of telangiectasia compared with 75% clearance with the PDL device, although no statistical analyses were reported. None of the studies provided a direct comparison with other therapies for rosacea.

Erceg et al. (2013) systematically reviewed the literature concerning pulsed dye laser (PDL) treatment for inflammatory skin diseases including rosacea. The authors noted that most conclusions formulated are not based on randomized controlled trials. The authors concluded that there is low level evidence for PDL treatment for papulopustular rosacea.

In a split-face, double-blind randomized controlled trial, Alam et al. (2013) compared the effectiveness of microsecond 1064-nm neodymium:yttrium-aluminum-garnet (Nd:YAG) laser with non-purpuragenic 595-nm pulsed dye laser (PDL) for diffuse facial erythema or erythematotelangiectatic rosacea. Bilateral cheeks received 4 treatments each at one month intervals with PDL or Nd:YAG. Spectrophotometer measurements, digital photographs, pain scores, and patient preferences were recorded. Fourteen patients (57% women, mean age 42 years) completed the study and were analyzed. Spectrophotometer readings changed after both PDL (8.9%) and Nd:YAG (2.5%), but varied by treatment type, with PDL reducing facial redness 6.4% more from baseline than Nd:YAG. Pain varied, with Nd:YAG associated with less pain, at 3.07, than PDL at 3.87. Subjects rated redness as improved by 52% as a result of PDL, and 34% as a result of Nd:YAG. No serious adverse events were observed. The authors concluded that facial erythema is safely and effectively treated with PDL and Nd:YAG and that non-pupuragenic PDL may be more effective for lighter-skinned patients, but microsecond Nd:YAG may be less painful. According to the authors, future research may consider comparison of additional laser devices and settings. This study is limited by a small sample size.

A Cochrane review on interventions for rosacea (van Zuuren et al, 2011) concluded that the quality of studies evaluating rosacea treatments was generally poor and that further well-designed, adequately powered randomized controlled trials are required. The authors indicated that lasers and light therapies appear to have a role to play in the treatment of rosacea but these treatment modalities are still largely under-researched.

Neuhaus et al. (2009) compared nonpurpuragenic pulsed dye laser (PDL) with intense pulsed light (IPL) treatment in the ability to reduce erythema, telangiectasia, and symptoms in patients with moderate facial erythematotelangiectatic (ET) rosacea. Twenty-nine patients were enrolled in a randomized, controlled, single-blind, split-face trial with nonpurpuragenic treatment with PDL and IPL and untreated control. PDL and IPL resulted in significant reduction in cutaneous erythema, telangiectasia, and patient-reported associated symptoms. No significant difference was noted between PDL and IPL treatment. The value of this study is limited by the small sample size.

Campolmi et al. (2011) assessed the efficacy and safety of intense pulsed light in treating non-aesthetic vascular skin lesions, especially with regard to poikiloderma of Civatte and rosacea. A total of 85 patients, 64 women and 21 men, with 63 non-aesthetic vascular lesions (28 Poikiloderma of Civatte and 35 rosacea), 22 pigmented lesions (UV-related hyperpigmentation of solar lentigo-type) and four precancerous lesions (actinic keratosis, AKs), were treated repeatedly with intense pulsed light (IPL) for 2 years. The patients received a mean of five treatments (range 4-6) at 3-weekly intervals. They were evaluated via clinical observations and professional photographs were taken before each treatment and after 2 weeks, 4 weeks, 3 months, 6 months and 12 months. The outcome of the IPL treatments was evaluated by four independent dermatologists, who were not informed about the study protocol, and who assessed the performance of IPL by dividing the results into four categories: no results, slight improvement, moderate improvement and marked improvement. All the patients showed improvements in their overall lesions: 72 lesions (80.9%) achieved a marked improvement, 14 lesions (15.7%) achieved a moderate improvement and three lesions (3.4%) achieved a slight improvement. The results of the 63 non-aesthetic vascular lesions in rosacea and poikiloderma of Civatte were: 51 with a marked improvement, 10 with moderate improvement, whereas only two lesions achieved a slight improvement. No undesirable effects were observed. According to the investigators, the study confirms how by minimizing side-effects, time and costs, IPL can be effective and safe for the treatment of non-aesthetic facial and neck vascular lesions. Study limitations include a small sample size and lack of a control group.

Madan et al. (2009) reviewed the outcome of 124 patients with rhinophyma treated with the CO(2) laser. Outcomes were determined by case notes, clinical review and questionnaire. Laser treatment was completed in a single session in 115 of 124 patients. All patients were reviewed 3 months post-treatment. Results were classified as good to excellent in 118 and poor in six patients. All patients were sent a satisfaction questionnaire in 2008 and 52 patients replied. Patients reported high levels of satisfaction following treatment. The post-treatment response at 3-month review was maintained long term. The main complications were pain associated with injection of local anaesthetic, scarring and hypopigmentation (four patients) and open pores (two patients). The investigators concluded that the CO(2) laser is an effective and durable treatment for rhinophyma. Treatment carries a low risk of side-effects and is associated with high patient acceptability and satisfaction. Study limitations include a small sample size and lack of a control group.

Lazzeri et al. (2013) reviewed the long-term results of 67 patients affected by rhinophyma treated with two different methods. Forty-five patients were treated with tangential excision and 22 with a CO2 laser. Minor complications, including scarring and hypopigmentation, were seen in 6 patients. All patients were satisfied with their outcomes at the follow-up visit, and no major complications were detected during follow-up. The authors concluded that both tangential excision and carbon dioxide laser are well-established, reliable procedures for rhinophymaplasty that preserve the underlying sebaceous gland fundi allowing spontaneous re-epithelialization without scarring with similar outcomes and high patient satisfaction. According to the authors, the CO2 laser is more capital intensive and results in higher fees compared with the simpler cold blade tangential excision. The authors state that the ease of use, accuracy and precision of laser treatment is not justified by the increased costs. According to the authors, the disadvantage of the deep tissue laser penetration is that the laser may generate high thermal energy with resultant damage to the dermis and adnexa, with the associated risks of scarring, poor texture and pigmentation modifications.

Har-El et al. (1993) compared laser surgery and sharp blade excision of rhinophyma in a retrospective study of 23 patients treated surgically for rhinophyma. Sixteen patients had laser surgery and 7 patients underwent sharp blade excision. Outcome measures included length of the procedure, preservation of normal tissue, the need for skin grafting, intraoperative pain and discomfort, intraoperative bleeding, postoperative pain and discomfort, postoperative bleeding, complications, and end results (all listed in the literature as advantages of laser surgery). When comparing the surgeries, there were no difference in length of surgery, preservation of normal tissue, complications, postoperative pain the need for skin grafting, and end results. There was less intraoperative and postoperative bleeding, easier and smoother procedure, and more comfortable postoperative care with laser surgery. The authors concluded that their results do not agree with most of the list of advantages attributed to laser rhinophyma surgery in the literature.

Cosmetic results of rhinophymas treated with carbon dioxide laser or electrosurgery were compared in six patients 2 to 5 years after surgery. Although the results were comparably good, the use of the carbon dioxide laser proved to be more time-consuming and less convenient. Scar formation was observed in both patient groups equally and was related to the depth of tissue removal, independent of the instrument used (Gjuric and Rettinger, 1993).

Additional studies comparing surgical procedures are needed to determine evidence-based treatment for rhinophyma.

Professional Societies

The American Academy of Dermatology (AAD): The AAD does not have a clinical guideline on the treatment of rosacea.

American Acne & Rosacea Society on the Management of Rosacea (AARS): The AARS issued consensus recommendations on the management of rosacea that state that laser systems, such

as pulsed dye laser (PDL) and Nd:YAG, as well as intense pulsed light (IPL) devices can be used to effectively treat persistently dilated superficial cutaneous vessels that are not responsive to medical therapies used for treatment of papulopustular rosacea, including linear telangiectases and more confluent telangiectatic networks. The authors also state that approaches for the treatment of rhinophyma may include laser ablation (Tanghetti et al. 2014).

Pilonidal Sinus Disease

The clinical evidence was reviewed on March 13, 2014 with no additional information identified that would change the unproven conclusion for laser hair removal for treatment of pilonidal sinus disease.

Ghnnam and Hafez (2011) conducted a prospective randomized study that compared permanent laser hair removal following the excision of pilonidal disease with conventional methods for hair removal. Patients undergoing surgery for pilonidal disease were randomized to 2: those using laser hair removal methods following completed healing of wounds (group I, n=45) or regular post-healing conventional methods for hair removal, mainly razor and depilatory creams, for at least 6 months (group II, n=41). Group I patients received regular, monthly laser hair treatment sessions using Alexandrite laser for four sessions. Group I patients found the procedure comfortable with no complications. Group II patients reported difficulty in maintaining hair removal with conventional methods, and mostly, by the end of the first year, all cases stopped maintaining regular hair removal. There was no significant difference between the groups in the recurrence rate (0% for laser versus 4.4% for standard hair removal methods). Recurrence occurred in Group II patients (two cases) mostly due to failure in maintaining hair removal and area hygiene. The authors advocate the use of laser epilation after surgery for pilonidal sinus as it decreases the chance of recurrence. According to the authors, larger studies with long-term follow-up are still needed to approve this conclusion.

Badawy and Kanawati (2009) evaluated the effectiveness of laser hair removal (LHR) in the natal cleft area on the recurrence rate of pilonidal sinus (PNS) as an adjuvant therapy after surgical treatment. The study included 25 patients. Fifteen patients underwent LHR treatment using Nd:YAG laser after surgical excision of PNS (patients group) while ten subjects with PNS did not undergo LHR and served as a control group. The patients received 3 to 8 sessions of LHR. The follow up period lasted between 12 to 23 months. None of the patients who underwent LHR required further surgical treatment. Seven patients out of ten in the control group developed recurrent PNS. The investigators concluded that LHR should be advised as an essential adjuvant treatment after surgical excision of PNS. This study is limited by a small sample size and lack of randomization.

Sixty patients who underwent surgical treatment of pilonidal sinus disease and were treated with a 755-nm alexandrite laser after surgery were examined retrospectively. The charts were reviewed, and the patients were interviewed on the telephone about their post-laser period and recurrence. The overall recurrence rate was 13.3%, after a mean follow-up period of 4.8 years. The mean number of laser treatments was 2.7. Seventy-five percent of the recurrences were detected after a follow-up period of 5 to 9 years. Fifty percent of the recurrent cases had drainage and healing by secondary intention before the laser epilation. The investigators concluded that laser hair removal after surgical interventions in pilonidal sinus disease decreases the risk of recurrence over the long term (Oram 2010). This study had no control group which limits the validity of the study's conclusion.

In a retrospective review, Lukish et al. (2009) investigated the use of laser epilation (LE) of the intergluteal hair in 28 adolescents with pilonidal disease (PD) as a method of permanent hair removal. Eight patients presented with abscess and were managed by incision and drainage followed by excision and open wound management, 17 patients presented with a cyst or sinus and underwent excision and primary closure, and 3 patients with asymptomatic sinus were managed nonoperatively. Laser epilation was performed after complete wound healing or immediately in those patients with asymptomatic sinus disease. Intergluteal hair was completely

removed in all patients. Patients required an average of 5 +/- 2 LE therapy sessions for hair removal. One female developed a recurrence. The mean follow-up for the group was 24.2 +/- 9.9 months. The investigators concluded that laser epilation may reduce recurrence of PD. Study limitations include a small sample size and lack of a control group.

Over a 5-year period, 14 patients with recurrent pilonidal disease were treated with laser depilation. They were all contacted by postal questionnaire, and those with ongoing disease were asked to return to the clinic for evaluation and possible further treatment. All patients returned the postal questionnaire. At 5 years, 4 patients had on-going disease and received further depilation with the Alexandrite laser. These 4 patients were followed for one year and remained healed during that time. All patients found the procedure painful and received local anaesthetic. The investigators concluded that laser depilation in the natal cleft is not a cure for pilonidal disease. Removal of hair by this method represents an alternative and effective method of hair removal and, although long lasting, is only temporary. However, it allows the sinuses to heal rapidly. It is relatively safe, and simple to teach, with few complications. It should thus be considered as an aid to healing the problem pilonidal sinus (Odili and Gualt, 2002). Study limitations include very small sample size and lack of a control group.

Schulze et al. (2006) assessed the efficacy of laser epilation as an adjunctive therapy to surgical excision of the pilonidal sinus. Eighteen men and five women were treated with laser epilation form 2001 to 2004. After surgical excision of the affected area, a Vasculite Plus laser was used for the epilation treatments. Each session involved 9 to 12 treatments and the patients underwent an average of two sessions. All 19 of the patients that remain in follow-up report no recurrence of their folliculitis or need for further surgical procedures. During treatment, six of the men and one of the women experienced a superficial wound dehiscence. All healed with local wound care and continued laser treatments. The investigators concluded that although not curative in and of itself, the removal of hair allows better healing and decreases the chance of recurrence. Limitations of the study include a small sample size and 17% of the patients were lost to follow-up.

There is insufficient evidence to conclude that laser hair removal is effective for treating pilonidal sinus disease. Most of the studies regarding this treatment were small and uncontrolled. Additional well-designed controlled trials are needed to determine the efficacy of laser hair removal for this condition.

Professional Societies

American Society of Colon and Rectal Surgeons (ASCRS): The ASCRS guidelines for managing pilonidal disease recommend hair removal via shaving along the intergluteal fold (gluteal cleft) in the absence of abscess, for acute and chronic pilonidal disease and as an adjunct to surgery or to prevent recurrence. The guidelines also indicate that while laser hair removal has demonstrated successful results for primary and recurrent pilonidal disease, there is insufficient evidence at this time to make any recommendation for this technique (Steele et al., 2013).

U.S. FOOD AND DRUG ADMINISTRATION (FDA)

Phototherapy: A number of different phototherapy devices have been approved by the FDA. These include devices that deliver blue, green, and yellow light phototherapy; photothermolysis devices, intense pulsed dye lasers, and near-infrared lasers. See the following Web site for more information (use product codes FTC or GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed May 2014.

Photodynamic Therapy: The FDA has given approval for marketing to both Levulan Kerastick and the BLU-U(TM) Blue Light Photodynamic Therapy Illuminator on December 3, 1999 as components of a two-step therapy for the treatment of nonhyperkeratotic actinic keratoses (AK) of the face or scalp. Treated lesions that have not completely resolved after 8 weeks may be treated a second time. See the following Web site for more information:

http://www.accessdata.fda.gov/cdrh_docs/pdf3/k031805.pdf. Accessed May 2014.

Pulsed Dye Laser (PDL): PDLs are classified as Class II devices. In 1986, the Candela Corporation manufactured the first PDL approved by the FDA for the treatment of cutaneous vascular lesions. Since then, various models have been developed and deemed substantially equivalent by the FDA. See the following Web site for more information: See the following Web site for more information (use product code GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. Accessed March 2014.

Laser Therapy: Several flashlamp-pumped pulsed dye lasers (FLDPLs), Xenon-chloride (XeCl) excimer lasers, and erbium:yttrium-aluminum-garnet (Er:YAG) lasers have received FDA approval. See the following Web site for more information (use product code GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm . Accessed March 2014.

Additional Products
Pulsed-dye lasers include but are not limited to the following: C-beam Pulse Dye Laser System (Candela Corp.); PhotoGenica V Star and PhotoGenica V lasers (Cynosure, Inc.)

The complete list of commercially available devices for light therapy and laser therapy for rosacea is extensive. Some examples are the PhotoGenica V (Cynosure Inc.); Photoderm® VL/PL; and VascuLight™ Elite, HR, SR, and VS (Lumenis Inc.); 532-nm KTP laser (Gemini, Laserscope); 585-nm flash lamp pulsed dye laser 595-nm flashlamp pumped long-pulsed PDL (V-beam, Candela); GenteLASE (Candela Laser Corp., Candela Corp.); LightSheer EP (Lumenis Inc./Yokneam); Coolglide Vantage (Altus/Cutera Inc.); Apogee 5500, Apogee 6200 (Cynosure Inc.); Vasculite Plus Intense Pulsed Light laser (Lumenis Inc.)

Photodynamic therapy products include but are not limited to the following: BLU-U(TM) (DUSA Pharmaceuticals Inc, Wilmington, MA), Levulan® Kerastick® (DUSA Pharmaceuticals Inc, Wilmington, MA), Metvix® or Metvixia® (PhotoCure ASA, Oslo, Norway).

The following phototherapy devices are available for treatment of acne vulgaris. Blue Light: ClearLight Acne Photoclearing System (Lumenis, Santa Clara, CA), BLU-U 4170 (DUSA Pharmaceuticals, Wilmington, MA), OmniLux Blue (Phototherapeutics, Manchester, UK). Green Light: 532 nm Aura Laser and 532/1064 nm Gemini laser (Laserscope, San Jose, CA). Intense Pulsed Light Sources: ClearTouch (Radiancy Inc., Orangeburg, NY), Ellipse (DDD, Horsholm, Denmark), Estelux™ System (ICN Photonics Ltd., Llanelli, UK). Near-infrared Lasers: Smoothbeam (Candela, Wayland, MA), CoolTouch CT3 (CoolTouch Inc., Roseville, CA), Aramis (Quantel, Clermont-Ferrand, France).

CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)

Medicare recognizes the use of lasers for many medical indications. Refer to the NCD for Laser Procedures (140.5).

Medicare does not have a specific NCD for use of light or laser therapy for the treatment of cutaneous lesions. Local Coverage Determinations (LCDs) do exists. Refer to the LCDs for Removal of Benign or Premalignant Skin Lesions, Removal of Benign Skin Lesions and Skin Lesion (Non-Melanoma) Removal.

There are no specific NCDs for laser hair removal for the treatment of pilonidal sinus disease. There are LCDs which mention electrolysis epilation. Refer to the LCDs for Noncovered Services.

(Accessed May 14, 2014)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
08/01/2014	• Changed policy title; previously titled *Laser Therapy for Cutaneous Vascular Lesions and Pilonidal Disease* • Reorganized policy content • Updated benefit considerations; added language for *Essential Health Benefits for Individual and Small Group* plans to indicate: • For plan years beginning on or after January 1, 2014, the Affordable Care Act of 2010 (ACA) requires fully insured non-grandfathered individual and small group plans (inside and outside of Exchanges) to provide coverage for ten categories of Essential Health Benefits ("EHBs") • Large group plans (both self-funded and fully insured), and small group ASO plans, are not subject to the requirement to offer coverage for EHBs; however, if such plans choose to provide coverage for benefits which are deemed EHBs (such as maternity benefits), the ACA requires all dollar limits on those benefits to be removed on all Grandfathered and Non-Grandfathered plans • The determination of which benefits constitute EHBs is made on a state by state basis; as such, when using this guideline, it is important to refer to the enrollee's specific plan document to determine benefit coverage • Revised coverage rationale: • Added language to indicate if service is "medically necessary" or "not medically necessary" to existing proven/unproven statements • Replaced language indicating "laser therapy including intense pulsed light is unproven for the treatment of rosacea" with "light and laser therapy including intense pulsed light are unproven and not medically necessary for the treatment of rosacea and rhinophyma" • Added language to indicate light and laser therapy including light phototherapy, photodynamic therapy, intense pulsed light, and pulsed dye laser are unproven and not medically necessary for treating active acne vulgaris • Updated list of applicable ICD-9 diagnosis codes; added 706.1 • Updated list of applicable ICD-10 diagnosis codes (preview draft effective 10/01/15): o Reorganized code listings by diagnosis category o Added L70.0, L70.1, L70.3, L70.4, L70.5, L70.8, L70.9 and L73.0 • Updated supporting information to reflect the most current description of services, clinical evidence, FDA and CMS information and references • Archived previous policy version 2014T0337J

Archived Policy Versions (For Internal Use Only)

Effective Date	Policy Number	Policy Title
06/01/2014 - 07/31/2014	2014T0337J	Laser Therapy for Cutaneous Vascular Lesions and Pilonidal Disease
07/01/2013 - 05/31/2014	2013T0337I	Laser Therapy for Cutaneous Vascular Lesions and Pilonidal Disease
07/01/2012 - 06/30/2013	2012T0337H	Laser Therapy for Cutaneous Vascular Lesions and Pilonidal Disease
08/01/2011 - 06/30/2012	2011T0337G	Laser Therapy for Cutaneous Vascular Lesions and Pilonidal Disease
11/01/2010 – 07/31/2011	2010T0337F	Laser Therapy for Cutaneous Vascular Lesions and Pilonidal Disease
05/15/2009 – 10/31/2010	2009T0337E	Light and Laser Therapy for Skin Conditions
05/15/2008 – 05/14/2009	2008T0337D	Light and Laser Therapy for Skin Conditions