LIGHT AND LASER THERAPY FOR CUTANEOUS LESIONS AND PILONIDAL DISEASE

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Instructions for Use

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COVERAGE RATIONALE

See Benefit Considerations

Pulsed dye laser therapy is proven and medically necessary for treating the following:
- Port-wine stains
- Cutaneous hemangiomata

Light and laser therapy including but not limited to intense pulsed light, light phototherapy, photodynamic therapy, and pulsed dye laser are unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:
- Rosacea
- Rhinophyma
- Acne vulgaris

Laser hair removal is unproven and not medically necessary for treating pilonidal sinus disease due to insufficient evidence of efficacy.

APPLICABLE CODES

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan 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 claim payment. Other Policies and Coverage Determination Guidelines may apply.

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.

CPT Code	Description
Cutaneous Vascular Lesion	
17106	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
17107	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); 10.0 to 50.0 sq cm

CPT Code	Description
Cutaneous Vascular Lesion	
17108	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq cm
Laser Hair Removal	
17380	Electrolysis epilation, each 30 minutes

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ICD-10 Diagnosis Code	Description
Cutaneous Vascular	
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

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.

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 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. Acne is a multifactorial inflammatory disease, and the current understanding of acne pathogenesis is continuously evolving (Zaenglein et al., 2016). 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, 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. Although originally thought to be congenital in nature secondary to abnormal skin in the gluteal cleft, the current widely accepted theory describes the origin of pilonidal disease as an acquired condition intimately related to the presence of hair in the cleft (Steele, et al., 2013).

BENEFIT CONSIDERATIONS

Certain states allow coverage of 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 member specific benefit plan document must be reviewed to determine what benefits, if any, exist for laser therapy for treatment of port-wine stains and cutaneous hemangiomata.

CLINICAL EVIDENCE

Port-Wine Stains (PWS) and Hemangiomata

Chinnadurai et al. (2016) systematically reviewed studies of laser treatment of infantile hemangioma (IH). A total of 29 studies addressing lasers: 4 randomized controlled trials, 8 retrospective cohort studies, and 17 case series were identified. Lasers varied across studies in type, pulse width, or cooling materials. Most comparative studies (n = 9) assessed variations of pulsed dye laser (PDL) and examined heterogeneous endpoints. Most studies reported on treatment of cutaneous lesions. CO2 laser was used for subglottic IH in a single study, and was noted to have a higher success rate and lower complication rate than both Nd:YAG and observation. Studies comparing laser with β-blockers or in combination with β-blockers reported greater improvements in lesion size in combination arms versus β-blockers alone and greater effects of lasers on mixed superficial and deep IH. Strength of the evidence for outcomes after laser treatments ranged from insufficient to low for effectiveness outcomes. Strength of the evidence was insufficient for the effects of laser compared with β-blockers or in combination with β-blockers as studies evaluated different agents and laser types. Studies assessing outcomes after CO2 and Nd:YAG lasers typically reported some resolution of lesion size, but heterogeneity among studies limited the ability to draw conclusions. The authors concluded that studies of laser treatment of IH primarily addressed different laser modalities compared with observation or other laser modalities. PDL was the most commonly studied laser type, but multiple variations in treatment protocols did not allow for demonstration of superiority of a single method. Most studies reported a higher success rate with longer pulse PDL compared to observation in managing the size of IH, although the magnitude of effect differed substantially. Studies generally found PDL more effective than other types of lasers for cutaneous lesions. When first introduced as a primary treatment for IH, various laser modalities generally offered superior outcomes compared with steroid therapy and observation. According to the authors, in the era of β-blocker therapy, laser treatment may retain an important role in the treatment of residual and refractory lesions.

Shen et al. (2015) conducted a meta-analysis to review the therapeutic efficacy and safety of pulsed dye laser (PDL) in the treatment of infantile hemangiomas (IH). A total of 13 articles with 1529 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.

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.

Chen et al. (2015) retrospectively summarized the use of pulsed dye laser in infant patients with superficial hemangioma, who had received 595 nm tunable pulsed dye laser treatment in the last 10 years. Detailed demographics, results of assessment about their degree of clearance and clinical examination for treatment complications were entered into SASS10.0 version database, and statistical analyses were conducted. Six hundred and fifty-seven cases with superficial hemangioma were recruited. The overall effectiveness rate was 91.17%. Female patients respond better than male, the difference was statistically significant. Lesions at different part of the body respond differently to the treatment with lesions on extremities show the best result. The response rate does not

increase with time of treatments. The most common side-effects were pigment changes and skin atrophy, which usually resolve spontaneously and disappear completely in a few months. The authors concluded that their experience confirmed the satisfactory clinical efficacy and safety of the 595 nm tunable pulse dye laser in the treatment of childhood superficial hemangioma.

According to a Comparative Effectiveness Review of infantile hemangioma prepared for the Agency for Healthcare Research and Quality (AHRQ), limited research is available to guide decision-making about the use of laser modalities as the initial intervention. The advent of propranolol has largely relegated laser treatment to secondary management. There is little comparative data between lasers and beta-blockers, however the success rates for complete or near complete resolution in historical laser studies are notably lower than those in more recent propranolol studies. Under current treatment paradigms, PDL with epidermal cooling is most often used for residual cutaneous changes after the completion of the proliferative growth phase and with incomplete resolution after pharmacologic management, while Nd:YAG laser is most often used intralesionally for medically refractory lesions. A variety of other lasers are used for intralesional treatment or resection, though no conclusions can be drawn regarding the superiority of any of these modalities over any other. According to the review, laser studies generally found PDL more effective than other types of laser, but effects remain unclear as studies are heterogeneous and the role of laser vis-a-vis beta-blockers is not clearly described in the literature (Chinnadurai et al., 2016).

Professional Societies

American Academy of Pediatrics (AAP)

An AAP clinical report for the diagnosis and management of infantile hemangioma (IH), states that laser treatment of IH may be useful in early, non-proliferating, superficial lesions; management of critical skin; treatment of ulcerating lesions; "multimodal" therapy; and management of persisting post-involution telangiectasia. According to the report, pulsed dye laser (PDL) is used most commonly because its light is preferentially absorbed by hemoglobin (Darrow et al., 2015). This clinical report is not a formal practice guideline, but it may form the basis of a future practice guideline from the AAP.

Acne Vulgaris

In a systematic review, de Vries et al. (2018) assessed the efficacy and safety of non-pharmacological therapies in the treatment of acne vulgaris. These included laser- and light-based therapies, chemical peels and fractional microneedling radiofrequency. Seven studies were considered to include a high methodological quality, and included in the best evidence synthesis. Moderate evidence was found for intense pulsed light (400-700 and 870-1200 nm) and the diode laser (1450 nm). Initially, conflicting evidence was found for pulsed dye laser (585-595 nm). Circumstantial evidence was the basis for non-pharmacological therapies in the treatment of acne vulgaris, for which the authors were unable to draw clear conclusions. They concluded that these outcomes provide a first step in future research.

In an updated Cochrane review, Barbaric et al. (2018) evaluated the effects of light-based interventions for acne vulgaris. Seventy-one randomized controlled trials ((4211 participants, median sample size 31) were included. Results from a single study (n = 266) showed little or no difference in effectiveness on participants' assessment of improvement between 20% aminolaevulinic acid (ALA) photodynamic therapy (PDT), activated by blue light, vs. vehicle plus blue light, whereas another study (n = 180) comparing ALA-PDT (red light) concentrations showed that 20% ALA-PDT was no more effective than 15% ALA-PDT but better than 10% and 5% ALA-PDT. Pooled data from three studies (n = 360) showed that methyl aminolaevulinate PDT, activated by red light, had a similar effect on changes in lesion counts vs. placebo cream with red light. Several studies compared yellow light with placebo or no treatment, infrared light with no treatment, gold microparticle suspension with vehicle and clindamycin/benzoyl peroxide (C/BPO) combined with pulsed dye laser with C/BPO alone. None of these showed any clinically significant effects. Most studies reported adverse effects, but inadequately, with scarring reported as absent, and blistering only in studies on intense pulsed light, infrared light and PDT (very low quality of evidence). The authors recommend carefully planned studies, using standardized outcome measures and common acne treatments as comparators.

A Cochrane review conducted by Barbaric et al. (2016) evaluated the effects of light treatment of different wavelengths for acne. Seventy-one randomized controlled trials (4211 participants, median sample size 31) were included in the review. Light interventions differed greatly in wavelength, dose, active substances used in photodynamic therapy (PDT), and comparator interventions (most commonly no treatment, placebo, another light intervention, or various topical treatments). Numbers of light sessions varied from one to 112 (most commonly two to four). Frequency of application varied from twice daily to once monthly. Selection and performance bias were unclear in the majority of studies. Two thirds of studies were industry-sponsored; study authors either reported conflict of interest, or such information was not declared, so the risk of bias was unclear. Results from a single study (n = 266, low quality of evidence (QE)) showed little or no difference in effectiveness on participants' assessment of improvement between 20% aminolevulinic acid (ALA) PDT, activated by blue light, versus vehicle plus blue light, whereas another study (n = 180) of a comparison of ALA-PDT (red light) concentrations showed 20% ALA-PDT was no more effective than 15%, but better than 10% and 5% ALA-PDT. Pooled data from three studies, (n = 360, moderate QE) showed that methyl aminolevulinate (MAL)-PDT, activated by red light, had a similar effect on changes in lesion

counts, compared with placebo cream with red light. Several studies compared yellow light to placebo or no treatment, infrared light to no treatment, gold-microparticle suspension to vehicle, and clindamycin/benzoyl peroxide (C/BPO) combined with pulsed dye laser to C/BPO alone. None of these showed any clinically significant effects. Although the primary endpoint of the review was long-term outcomes, less than half of the studies performed assessments later than eight weeks after final treatment. Only a few studies assessed outcomes at more than three months after final treatment. The authors concluded that high-quality evidence on the use of light therapies for individuals with acne is lacking. There is low certainty of the usefulness of MAL-PDT (red light) or ALA-PDT (blue light) as standard therapies for people with moderate to severe acne. According to the authors, carefully planned studies, using standardized outcome measures, comparing the effectiveness of common acne treatments with light therapies are needed.

Keyal et al. (2016) evaluated the evidence regarding safety and efficacy of photodynamic therapy (PDT) in treating acne lesions. Thirty-six clinical trials were included in the review. Twenty-four of these trials were performed to evaluate the effect of PDT in acne and 12 trials were performed to compare the effect of PDT with light or laser alone therapy. Among 24 trials that used PDT only, 3 were clinical trials with control, 14 were clinical trials without control, 6 were randomized controlled trials (RCTs) and 1 was retrospective study. The authors concluded that photodynamic therapy (PDT) is an effective treatment modality for acne lesions. However, more RCTs are needed to establish standard guidelines regarding concentrations and incubation period of photosensitizers and optimal parameters of light sources. There is also paucity of studies that could identify whether PDT can be a first line treatment for severe acne or only an alternative to medical treatment for non-responders. Moreover, RCT comparing conventional therapy with PDT are highly needed.

Boen et al. (2017) performed a systematic review of the literature for photodynamic therapy (PDT) used for acne and critically evaluated the studies. Sixty-nine clinical trials, four case reports, and two retrospective studies met the inclusion criteria. Seven of the studies were high quality. The most common photosensitizers used were 5-aminolevulinic acid and methyl aminolevulinate, and both showed similar response. Red light was the most frequently used light source, followed by intense pulsed light, and showed comparable results. Inflammatory and non-inflammatory lesions both responded to treatment, with inflammatory lesions showing greater clearance in most studies. Adverse events associated with PDT for acne were mild and included pain on illumination and post-procedural erythema and edema. The authors indicated that this review supports PDT as an efficacious treatment for acne and a good adjunctive treatment for mild to severe acne, especially in patients who have not responded to topical therapy and oral antibacterials and are not great candidates for isotretinoin. According to the authors, further studies are warranted to evaluate the optimal photosensitizers, light sources, incubation times, and number of treatments for PDT use in acne.

In a systematic review, Wat et al. (2014) reviewed the evidence to provide recommendations to guide physicians in the application of intense pulsed light (IPL) for the treatment of dermatologic disease. Studies that examined the role of IPL in primary dermatologic disease were identified, and multiple independent investigators extracted and synthesized data. Recommendations were based on the highest level of evidence available. Level 1 (moderate to high) evidence was found for the use of IPL for the treatment of acne vulgaris. The authors concluded that IPL is an effective treatment modality for a growing range of dermatologic disease and in some cases may represent a treatment of choice. According to the authors, the main limitation of this review was the general lack of high-quality studies. Almost all of the reviewed studies were limited by the number of patients enrolled (usually <100) and by the length of follow-up (typically ≤6 months). Long-term outcome analysis is needed. Additionally, the wide variety of IPL devices, device settings, patient demographic characteristics, and user expertise detracted from a completely homogeneous assessment of the data. According to the authors, further large-scale, high-quality studies are needed to optimally delineate exact treatment parameters for specific diseases.

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. The authors stated that the conclusions formulated from the systematic review are not based on randomized controlled trials.

In an evidence-based review, Zheng et al. (2014) assessed the effects and safety of photodynamic therapy (PDT) for acne. A total of 14 randomized controlled trials (RCTs) involving 492 patients were included. Photosensitizers included aminolevulinic acid (ALA), methylaminolevulinate (MAL), and indole-3-acetic acid (IAA). Light sources included red light, pulsed dye laser (PDL), intense pulsed light (IPL), long-pulsed dye laser (LPDL) and green light. The PDT protocols, including ALA + red light, ALA + PDL, ALA + IPL, MAL + red light, and MAL + LPDL, all showed great efficacy on inflammatory lesions. ALA + red light also had effects on non-inflammatory lesions and sebum secretion. ALA + IPL and IAA + green light significantly decreased sebum secretion. Triple treatment protocols showed great

improvement on inflammatory and non-inflammatory lesions. Increasing ALA concentration, ALA incubation time, PDT sessions, dose of light source or using occlusion for photosensitizers, or a combination of other treatments with PDT may achieve greater efficacy. The common side effects of PDT were tolerable and transient. The authors concluded that limited evidence indicates that PDT shows good efficacy in the treatment of acne with acceptable side effects. ALA + red light was shown to be the optimal choice. According to the authors, more RCTs are needed to determine the types and concentrations of photosensitizers and light sources, and the duration of light activation and incubation.

Antoniou et al. (2016) conducted a 12-week multicenter, randomized, split-face clinical trial to evaluate the efficacy and safety of the KLOX BioPhotonic System, a LED blue light phototherapy device using specific photo-converter chromophores, in the treatment of moderate to severe acne vulgaris. A total of 104 patients with moderate to severe acne were eligible for inclusion in the study and screened for enrolment. Of these, 98 (94%) were randomized and 90 (92%) underwent at least one treatment session. Five patients decided to withdraw their consent before receiving a first treatment, and three patients were not treated as the study enrollment period was ended. Efficacy was assessed through changes in acne severity using the Investigator's Global Assessment (IGA) scale and inflammatory acne lesion counts, both evaluated against baseline at weeks 6 and 12. Safety was assessed through physical exam, vital signs, laboratory evaluations, and physician and patient reporting of adverse events. A reduction of at least two grades in IGA scale severity was demonstrated in 51.7% of patients at week 12. Furthermore, at week 12, subjects with a baseline IGA grade of 3 (moderate) demonstrated a success rate (2 or greater grade drop) of 45.3% whereas patients with a baseline IGA grade of 4 (severe) demonstrated a success rate of 61.1%. Acne inflammatory lesion counts confirmed these results, with a reduction of at least 40% of lesions in 81.6% of treated hemi-faces after 12 weeks. Treatment was considered as safe and well tolerated, with no serious adverse event and no patient discontinuation from the study from any adverse event. The authors concluded that the BioPhotonic System comprised of LED blue-light phototherapy was efficacious and safe, with a sustained clinical response at 12 weeks for the management of moderate to severe facial inflammatory acne. According to the authors, study limitations include the absence of an established active acne topical agent as a control group. Another limitation of the study is that the majority of included patients were female, so the results mostly apply to this population.

Mohamed et al. (2016) compared the clinical efficacy of intense pulsed light (IPL) versus 1,064 long-pulsed Neodymium:Yttrium-Aluminum-Garnet (Nd: YAG) in treatment of facial acne vulgaris. Seventy four patients were enrolled in this prospective, split-face, randomized controlled trial. All participants received 3 sessions of IPL on the right side of the face and 1,064-nm Nd:YAG on the left side of the face at 4-weeks intervals. Final assessment was made by comparison of the changes in the count of inflammatory acne lesions (inflammatory papules, pustules, nodules and cyst) and non-inflammatory acne lesions (Comedones) and the acne severity score between both therapies, based on standardized photography. At the final visit, the inflammatory acne lesions were reduced on the IPL and 1,064-nm Nd:YAG treated sides by 67.1% and 70.2% respectively, while non-inflammatory acne lesions were reduced by 18.3% and 19.3% respectively. For both therapies, there was significant difference in the improvement on inflammatory acne lesions in comparison to non-inflammatory lesions. There was no significant difference in the efficacy of the two therapies in reducing the percentage of both types of acne lesions count from baseline to the end of the study The authors concluded that both IPL and 1,064-nm Nd:YAG laser are effective in treatment of inflammatory facial acne vulgaris. Study limitations include the absence of an established standard therapy as a control group.

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.

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.

Other studies evaluating light and laser therapy for treating acne were limited by small sample size and short follow-up (Nikolis et al., 2018; Yazdi et al., 2017; Voravutinon et al., 2016; Ash et al., 2016; Moftah et al., 2016; Pariser et al., 2015; Liu et al., 2014; Song et al., 2014; Moneib et al., 2014).

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., 2013).

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.

Professional Societies

American Academy of Dermatology (AAD)

In a guideline of care for the management of acne vulgaris, the AAD states that there is limited evidence to recommend the use and benefit of physical modalities for the routine treatment of acne, including pulsed dye laser. According to the AAD, large, prospective, multicenter, randomized, double-blinded controlled trials comparing light and laser devices to placebo are needed. AAD further states that comparative effectiveness clinical trials for safety and efficacy of different light and laser sources/wavelengths and which types of lesions they improve are also needed (Zaenglein et al., 2016).

American Society of Dermatologic Surgery (ASDS)

The ASDS board of directors proposed a committee of experts in the field to develop consensus documents on different treatments. An expert panel reviewed the literature on photodynamic therapy (PDT) and discussed the findings. According to the ASDS, PDT is highly effective in the treatment of inflammatory acne papules, but not comedones. PDT is an excellent option for moderate-to-severe acne when isotretinoin is not an option. Drawbacks of PDT for acne include time commitment, discomfort during treatment, posttreatment erythema, and crusting. According to the ASDS, there is no widely accepted protocol for treating inflammatory acne patients. This is a consensus based guide that was developed by considering evidence based reviews (Ozog et al., 2016).

Rosacea and Rhinophyma

In a systematic review, Wat et al. (2014) reviewed the evidence to provide recommendations to guide physicians in the application of intense pulsed light (IPL) for the treatment of dermatologic disease. Studies that examined the role of IPL in primary dermatologic disease were identified, and multiple independent investigators extracted and synthesized data. Recommendations were based on the highest level of evidence available. Level 2 (moderate) evidence was found for the treatment of rosacea. The authors concluded that IPL is an effective treatment modality for a growing range of dermatologic disease and in some cases may represent a treatment of choice. According to the authors, the main limitation of this review was the general lack of high-quality studies. Almost all of the reviewed studies were limited by the number of patients enrolled (usually <100) and by the length of follow-up (typically ≤6 months). Long-term outcome analysis is needed. Additionally, the wide variety of IPL devices, device settings, patient demographic characteristics, and user expertise detracted from a completely homogeneous assessment of the data. According to the authors, further large-scale, high-quality studies are needed to optimally delineate exact treatment parameters for specific diseases.

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., 2015) found that pulsed dye laser was more effective than yttrium-aluminium-garnet (Nd:YAG) laser based on one study, and it appeared to be as effective as intense pulsed light therapy (both low quality evidence). The authors stated that there was low quality evidence for laser and intense pulsed light therapy for ocular rosacea.

In a randomized, single-blinded, comparative study, Seo et al. (2016) compared the effectiveness of the dual wavelength long-pulsed 755-nm alexandrite/1,064-nm neodymium: yttrium-aluminum-garnet laser (LPAN) with that of 585-nm pulsed dye laser (PDL) for rosacea. Erythema index was measured by spectrophotometer, and digital photographs were evaluated by consultant dermatologists for physician's global assessment. Subjective satisfaction surveys and adverse effects were recorded. Forty-nine subjects with rosacea were enrolled in the study and 12 dropped out. Full face received four consecutive monthly treatments with LPAN or PDL, followed-up for 6 months after the last treatment. There were no significant differences between LPAN and PDL in the mean reduction of the erythema index, improvement of physician's global assessment, and subject-rated treatment satisfaction. PDL showed more adverse effects including vesicles than LPAN. No other serious or permanent adverse events were observed in both treatments. The authors concluded that both LPAN and PDL may be effective and safe treatments for rosacea. According to the authors, there are several limitations in the general application of the study findings. First, as with all studies comparing two devices, there is no way to be absolutely certain that the settings were comparable, since those have different parameters and laser settings. Second, because the spectrophotometer measured only small spots, erythema index might not reflect the entire severity of rosacea or facial erythema. Third, in subjects receiving LPAN treatments, it is difficult to determine the effect of each laser separately. Fourth, all the subjects were of Korean with darker skin types, which may limit the generalizability of the study. The authors state that future studies with split-face comparison, various laser settings, and comparison of long-pulsed alexandrite and PDL are necessary to establish the optimal treatment devices and settings for rosacea treatment.

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.

An expert panel of Canadian dermatologists developed guidelines to offer evidence-based recommendations to assist Canadian health care providers in the diagnosis and management of rosacea. The expert panel was recruited via invitations to the medical advisory board of the Acne and Rosacea Society of Canada and the Canadian Dermatology Association. The 2015 Cochrane review "Interventions in Rosacea" was used as a source of clinical trial evidence on which to base the guideline recommendations. The use of vascular laser or intense pulsed light therapy for erythema of rosacea was rated as a weak recommendation because of very low confidence in effect estimate. The use of ablative laser surgery, using CO2 or Er:YAG modalities for phymatous features of rosacea was rated as a weak recommendation because of very low confidence in effect estimate and variability in patient values and preferences (Asai et al., 2016).

In a review of rosacea, van Zuuren (2017) summarized that although laser therapy and other light-based therapies are widely used in the treatment of erythema and telangiectasia, these methods of treatment have been investigated primarily in observational studies. The few randomized trials are limited by small sample sizes.

A global Rosacea Consensus (ROSCO) panel was established to address the mistreatment of rosacea according to subtype as determined by clinical presentation. The panel reached consensus on several aspects of rosacea treatment and management, including treatment according to specific phenotype. With regard to specific treatment options,

laser and light therapies were included as first-line treatment options for persistent erythema and telangiectasia (Schaller et al., 2017).

Oge et al. (2015) published recommendations on the diagnosis and treatment of rosacea from the National Rosacea Society Expert Committee. Therapeutic modalities are chosen on the basis of the subtypes and clinical features identified; often a combination of these therapies is required. Laser and light therapies are included as first-line treatment options for both erythema and telangiectasia when used in combination with topical agents. Additional studies comparing surgical procedures are needed to determine evidence-based treatment for rosacea and rhinophyma.

Professional Societies

American Academy of Dermatology (AAD)

The AAD does not have a clinical guideline on the treatment of rosacea or rhinophyma.

American Acne & Rosacea Society (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

In a prospective randomized controlled study, Demircan et al. (2015) investigated the effects of laser epilation on patient satisfaction and recurrence in 60 patients who underwent pilonidal sinus surgery. Patients were divided in two groups of 30 patients each. Only the Karydakis flap reconstruction technique was performed in the first group. Two sessions of laser epilation were applied in the second group in addition to Karydakis flap reconstruction. The patients in the second group underwent laser epilation 2 weeks before and 3 weeks after the surgery for a total of 2 times in a private office. There were no statistically significant differences between the groups in terms of age, gender, smoking usage, American Society of Anesthesiologists (ASA) Score, duration of patient's complaints, body mass index (BMI) and hospital stay. There were no statistically significant differences between the groups in terms of surgical site infection, wound separation, or abscess formation postoperatively. There were statistically significant differences between the two groups in the first week post operation considering the visual analogue scale (VAS) pain score and VAS satisfaction score. While there were statistically significant differences between the two groups in the first month post operation considering the VAS pain score, there were no statistically significant differences between the groups in terms of VAS satisfaction score in the first and three month postoperatively. In the telephone interviews done 1 year after the surgery, recurrence was detected in 4% of first group and in 20% of second group. Recurrence rates were significantly higher in the second group. The authors concluded that their results show that laser epilation does not reduce the relapse rates in pilonidal sinus surgery, as expected. According to the authors, additional prospective randomized studies need to be done to evaluate laser epilation.

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.

Khan et al. (2016) conducted a retrospective study evaluating the use of laser depilation for treating 19 patients with recurrent pilonidal sinus following multiple surgical treatments. Patients were treated using long-pulsed alexandrite laser for depilation in the sinus area, an outpatient procedure. There was a significant reduction in hair density after laser treatment. The disease-free period after laser treatment was significantly longer than that one after surgical treatment. The average cost of repeated surgical treatment per disease-free month was significantly higher than that of laser treatment. According to the authors, compared to surgical treatment of recurrences, laser depilation is an efficient and cost-effective method of preventing recurrence and reducing morbidity and loss of man-hours. This study is limited by a small sample size and lack of a control group.

Pronk et al. (2018) conducted a systematic review to determine the effect of hair depilation on the recurrence rate in patients surgically treated for piloidal sinus disease. The search and selection yielded 14 studies, involving 963 patients. The study design of the included studies was: retrospective cohort (n = 7), prospective cohort (n = 3), randomized controlled trial (n = 2), and case-control (n = 2).The mean length of follow-up was 37.0 (standard error of the mean: 35.0) months. The recurrence rate was 9.3% (34 out of 366 patients) in patients who had laser hair removal, 23.4% (36 out of 154 patients) in those who had razor shaving/cream depilation, and 19.7% (85 out of 431 patients) in those who had no hair removal after surgery for pilonidal sinus disease. Although this review showed a lower recurrence rate after laser hair removal compared to no hair removal, the sample size is small with limited methodological quality of the included studies. High quality randomized controlled trials are needed to validate these findings.

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 et al., 2010). This study had no control group which limits the validity of the study's conclusion.

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 website for more information (use product codes FTC or GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 8, 2018)

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 website for more information: http://www.accessdata.fda.gov/cdrh_docs/pdf3/k031805.pdf. (Accessed May 8, 2018)

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 website for more information (use product code GEX):http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 8, 2018)

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 website for more information (use product code GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed May 8, 2018)

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 does not have National Coverage Determinations (NCDs) specifically for pulsed dye laser therapy used to treat port-wine stains and cutaneous hemangiomata. Local Coverage Determinations (LCDs) do not exist at this time.

Medicare does not have NCDs specifically for light and/or laser therapy (including intense pulsed light) used to treat rosacea and rhinophyma. LCDs do not exist at this time.

Medicare does not have NCDs specifically for light and/or laser therapy (including light phototherapy, photodynamic therapy, and intense pulsed light and pulsed dye laser) used to treat active acne vulgaris. LCDs do not exist at this time.

Medicare does not have NCDs specifically for laser hair removal used to treat pilonidal sinus disease. LCDs do not exist at this time.
(Accessed June 8, 2018)

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POLICY HISTORY/REVISION INFORMATION

Date	Action/Description
02/01/2019	• Reorganized policy template; simplified and relocated *Instructions for Use* and *Benefit Considerations* section • Archived previous policy version 2018T0337S

INSTRUCTIONS FOR USE

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the member specific benefit plan document must be referenced as the terms of the member specific benefit plan may differ from the standard plan. In the event of a conflict, the member specific benefit plan document governs. Before using this policy, please check the member specific benefit plan document and any applicable federal or state mandates. UnitedHealthcare reserves the right to modify its Policies and Guidelines as necessary. This Medical Policy is provided for informational purposes. It does not constitute medical advice.

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