Light and Laser Therapy (for Tennessee Only)

Policy Number: CS069TN.P
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Instructions for Use

Table of Contents **Page**

Related Policies

- Cosmetic and Reconstructive Procedures (for Tennessee Only)
- Outpatient Surgical Procedures –Site of Service (for Tennessee Only)

Application

This Medical Policy applies to Medicaid and CoverKids in the state of Tennessee.

Coverage Rationale

Pulsed dye laser therapy is proven and medically necessary for treating the following:

- Port-wine stains
- Cutaneous hemangioma/hemangiomata

Laser hair removal is proven and medically necessary for the treatment of pilonidal sinus disease that has been or is being treated with surgery performed to debride an accumulation of fluid or pus causing the formation of a cyst or abscess.

Fractional ablative laser fenestration [e.g., carbon dioxide (CO_2) laser, Erbium Yttrium Aluminum Garnet (Er:YAG) laser] of hypertrophic burn scars is proven and medically necessary when both of the following criteria are met:

- The burn scar is causing functional impairment (i.e., limiting range of motion) and the treatment can be reasonably expected to improve the functional impairment; **and**
- The individual has tried and failed at least one conventional treatment (e.g., hypoallergenic paper tape, pressure garments or silicone kits with gel/sheeting)

Light and laser therapy including, but not limited to, intense pulsed light, light phototherapy, photodynamic therapy, Neodymium: Yttrium-Aluminum-Garnet (Nd:YAG), excimer, and pulsed dye laser are unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:

- Rosacea
- Rhinophyma
- Acne vulgaris

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 federal, state, or contractual requirements 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 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
17108	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq cm
Hypertrophic Burn Scars	
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm2 or part thereof, or 1% of body surface area of infants and children
0480T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm2, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
Laser Hair Removal	
17380	Electrolysis epilation, each 30 minutes

Diagnosis Code	Description
Cutaneous Vascular Lesion	
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
Q85.89	Other phakomatoses, not elsewhere classified
Hypertrophic Burn Scars	
L91.0	Hypertrophic scar
L90.5	Scar conditions and fibrosis of skin
Laser Hair Removal	
L05.01	Pilonidal cyst with abscess
L05.02	Pilonidal sinus with abscess
L05.91	Pilonidal cyst without abscess
L05.92	Pilonidal sinus without abscess

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 to relieve symptoms and alleviate or prevent medical or psychological complications.

Hypertrophic Burn Scars

Hypertrophic burn scars result from an abnormal response with the body's wound-healing process. They appear as thick, red, raised scars that occur within a couple of months following a burn injury and are confined to the site of the injury. These types of scars may lead to an impairment of an individual's ability to return to baseline levels of motion due to pain, stiffness, and contracture. Studies have shown that fractional ablative laser therapy is effective in reducing scar thickness and neuropathic pain, as well as increasing pliability and improving movement of affected joints.

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 (AV) 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, IPL, and photodynamic therapy (PDT). PDT is the use of visible light in addition to a topical application of a photosensitizer, such as 5-aminolevulinic acid (ALA) or methyl aminolevulinate (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 (LHR) or laser hair depilation (LHD) has been found to be effective 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).

Clinical Evidence

Port-Wine Stains (PWS) and Hemangiomata

Wang et al. (2023) conducted a systematic review and meta-analysis to assess the safety and efficacy of photodynamic therapy (PDT) for port wine stains (PWS). The review included 26 studies (3 RCTs and 23 cohort studies) where PDT was administered to 3,034 patients with PWS. The authors noted that the characteristics of the treatment protocols varied between studies as there were three different kinds of photosensitizers utilized, the number of treatments (1-8.2 treatments), the therapy interval (4 weeks to 2-3 months), and the follow-up period (2 months to 5 years). In their evaluation of bias risk, the authors determined that 23 out of 26 non-randomized experiments were of poor quality and the three RCTs were of moderate quality. The authors reported that 51.5% of the patients achieved a 60% improvement after treatment with PDT and that 20.5% of patients achieved a ≥ 75% improvement (GRADE score: very low), The authors stated that PDT efficacy varied based on sex, age, the type and location of the PWS, and the PDT treatment parameters. The authors concluded that PDT is a safe and effective treatment for PWS.

In a systematic review and network meta-analysis (NMA), Fei et al. (2020) reviewed the efficacy and adverse effects of different therapies to address infantile hemangioma (IH). They evaluated 30 randomized controlled trials (RCTs) with more than 20 different therapeutic regimens and a combined 2123 children who were diagnosed with IH. The authors completed an NMA to synthesize the results of direct and indirect comparisons of the various regimens simultaneously to obtain a more accurate and precise statistical result. They found the pulse dye laser (PDL) was usually the first choice of vascular laser therapy and mostly reported and applied in IHs laser therapy and that a longer pulse has a higher efficiency due to its advantage in transdermal depth. One of their findings was that the treatment regimen of plus PDL with oral propranolol had the lowest incidence of adverse events. The study concluded that a combination of beta blockers and laser might be the first-line treatment of IHs, and a longer pulsed dye laser is preferred. The authors acknowledged that the quality of some indirect comparisons was low according to GRADE and that the study participants were not grouped by sex. The authors recommend additional well-designed RCTs to confirm their findings.

According to a Comparative Effectiveness Review of IH 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 intralesional 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., 2016a).

Chinnadurai et al. (2016b) systematically reviewed studies of laser treatment of infantile hemangioma (IH). A total of 29 studies addressing lasers: 4 RCTs, 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 PDL and examined heterogeneous endpoints. Most studies reported on treatment of cutaneous lesions. CO_2 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 Neodymium: Yttrium-Aluminum-Garnet (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 CO_2 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 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 PDL in the treatment of 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 event (AE). The authors concluded that PDL may be the effective modality to decrease the proliferative phase and accelerate rates of involution and resolution with few AEs.

Chen et al. (2015) retrospectively summarized the use of PDL in infant patients with superficial hemangioma, who had received 595 nm tunable PDL 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 responded better than male; the difference was statistically significant. Lesions in different parts of the body respond differently to the treatment, with lesions on extremities showing the best result. The response rate does not increase with time of treatments. The most common AEs were pigment changes and skin atrophy, which usually resolved 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 PDL in the treatment of childhood superficial hemangioma.

Faurschou et al. (2009) conducted a randomized side-by-side trial to compare efficacy and AEs between PDL and IPL in treating PWS. Twenty patients with PWS (face, trunk, extremities; pink, red and purple colors; skin types I-III) received one side-by-side treatment with PDL (V-beam Perfecta, 595 nm, 0.45-1.5 ms; Candela Laser Corporation, Wayland, MA, U.S.A.) and IPL (StarLux, Lux G prototype handpiece, 500-670 and 870-1400 nm, 5-10 ms; Palomar Medical Technologies, Burlington, MA, U.S.A.). Settings depended on the preoperative lesional color. Treatment outcome was evaluated by blinded, clinical evaluations and by skin reflectance measurements. While both technologies lightened the PWS and no AEs were observed with either device, the authors concluded that the PDL resulted in better efficacy and higher patient preference.

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

AAP clinical practice guidelines for the management of infantile hemangiomas state that clinicians may recommend laser therapy as a treatment option in managing select IHs (grade C, moderate recommendation). Decisions regarding use should be made in consultation with a hemangioma specialist, especially in young infants. Laser treatment may be most useful for the treatment of residual skin changes after involution and, less commonly, may be considered earlier to treat some IHs. The guidelines also note that, with the advent of beta-blocker therapy, laser approaches are used less frequently (Krowchuk et al., 2019).

Pilonidal Sinus Disease

In a single-center, retrospective observational study, Salimi-Jazi et al. (2023) investigated the number of laser sessions required to achieve certain amounts of hair reduction and the correlation with recurrence of pilonidal disease (PD). All of the 198 study participants underwent laser epilation (LE) with or without additional surgical procedure such as trephination or incision and drainage. The mean age at the time of the first LE treatment was 18 ±3.6 years. Data collected from each patient included demographics, Fitzpatrick skin type classification (1-6), hair color (light or dark), hair thickness (fine, medium, thick), number of LE sessions, any procedures done (incision and drainage, trephination of pilonidal pits, re-excision), follow up period and any recurrences. There were 21 patients that had skin type 1/ 2, 156 with skin type 3/ 4, and 21 patients with skin type 5/ 6. Forty-seven patients had light colored hair and 151 had dark colored hair; 29 patients had fine hair, 65 had medium hair and 40 had thick hair. Surgical procedures were done on 176 of the patients with 44 requiring incision and drainage and 132 undergoing trephination. The authors reported that during the study period and compared to their initial hair amount, 188 (95%) patients reached 20% hair reduction, 138 patients (70%) reached 50%, 78 (40%) reached 75%, and 38 (19%) reached 90%. Overall, the mean laser sessions to reach 20%, 50%, 75%, and 90% hair reduction was 2.6, 4.3, 6.6, and 7.8 sessions, respectively. The recurrence rate in their study was 6%. The authors stated that more mean LE sessions correlated with a higher percentage of

hair reduction regardless of the patients' hair and skin characteristics. Limitations included the retrospective, single-center design, the lack of a control group, the low number of patients with certain skin and hair types and that the low recurrence rate may not provide enough power to detect all the factors that could affect recurrence of pilonidal disease. The authors concluded that patients with dark color and thick hair require more LE sessions to achieve a certain degree of hair reduction and are more likely to experience pilonidal disease recurrence. The authors also concluded that increasing amount of hair reduction correlated with lower chance of recurrence and that targeting 75% hair reduction can be a clinically relevant treatment goal to reduce recurrence.

Check et al. (2022) conducted a prospective case series of 78 patients with mild pilonidal disease (PD) who were treated at a dedicated Pilonidal Care Clinic with a treatment protocol aimed at source control with improved hygiene, excision of pilonidal pits, and laser ablation of midline follicles to prevent new pits from forming, with no nidus resection. The mean age was 16.3 years and 55% of the population were female. All patients were started on an enhanced hygiene routine on their first clinic visit and were offered pit excision when there was minimal active inflammation in their crease and were also offered laser follicle ablation if hirsute. Seventy-three patients underwent laser epilation and 68 underwent pit excision. For patients with multiple, closely located pits, sequential alternating pit excision sessions were scheduled to improve wound healing and laser ablations were continued until resolution of crease hirsutism. Repeat visits were scheduled every 6 to 8 weeks until all pit wounds were healed and crease follicles were ablated with a minimum follow-up period of 1 year. The authors reported that 77 of the 78 patients had resolution of their PD after a mean of 3 ±2.5 laser epilations and 1.3 ±1 pit excisions during 4 ±2 clinic visits over a duration of 30 ±19 weeks. Sixty-seven of the 68 patients who underwent pit excision resolved, as did 9 patients who underwent laser epilation alone and 1 with hygiene alone. One patient continued to receive care for asymptomatic new pits. Limitations of the study included the single-center design, the high rate of attrition of almost 25% and the lack of follow-up beyond one year. The authors concluded that treating mild PD with improved hygiene, pit excision and laser epilation resulted in minimal morbidity and no activity restrictions.

In a systematic review that assessed the efficacy and safety of chronic pilonidal disease (PD) treatment with laser therapy, Romic et al. (2022) evaluated nine published studies and their own unpublished study. The studies they included were a mix of prospective and retrospective studies, case series, and comparative studies of radial emitting laser in the treatment of PD where the technical use of the laser probe was mostly consistent across all studies. The authors reported that these studies involved various sample sizes from 20 to 237 with a total of 971 participants of which 79.6% were males. The systematic review indicated 917 (94.4%) participants achieved primary healing with 10% of the participants experiencing minor complications. The authors concluded that the published literature demonstrated that laser therapy treatment is promising for the management of mild chronic PD. Limitations identified by the authors include the lack of reporting of patient comorbidities that might affect the outcome, the lack of stratification by sex or disease severity and the finding that most of the included studies were retrospective cohorts with small sample sizes and relatively short follow-up. They recommend that the classification of PD severity and standardized outcome reporting be determined to define indications and contraindications for laser treatment of PD as are RCTs to determine optimal timing for laser treatment after acute abscess, identification of the type of chronic PD that is amenable to laser therapy, the optimal amount of laser energy that should be delivered during the procedure and the long-term effectiveness and superiority of laser treatment over other treatment options.

Halleran et al. conducted a systematic review of published literature analyzing laser hair depilation (LHD) in pilonidal disease to determine its effect on disease recurrence. Thirty-five published studies were included. Of these, 28 studies were retrospective and 7 were prospective. There were 5 comparative studies: 2 retrospective, 1 prospective observational, and 2 RCTs. The number of patients included in each study ranged from one to 86 patients and patients received between one and 11 laser treatments. The pilonidal disease recurrence rate after LHD ranged from 0% to 28% at a mean follow-up ranging from 6 months to 5 years across studies. Four of the five studies that included a comparative group demonstrated a decreased recurrence rate compared to the non-laser cohort. The reviewers concluded that LHD is a promising therapy in the management of pilonidal disease. However, the literature published to date is heterogeneous and has limited generalizability. Additional research is needed to determine the effectiveness of LHD to prevent pilonidal disease recurrence (2018).

Pronk et al. (2018) conducted a systematic review to determine the effect of LHD on the recurrence rate in patients surgically treated for pilonidal 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), RCT (n = 2), and case-control (n = 2). The mean length of follow-up was 37 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 LHR compared to no hair removal, the sample size is small with limited methodological quality of the included studies. High quality RCTs are needed to validate these findings.

Lopez et al. (2017) conducted a prospective, single arm, pilot trial of LHD to the natal cleft to assess the safety and tolerability of the procedure in 13 adolescents with pilonidal disease. Each patient received an outpatient LHD treatment every four weeks with a goal of five total treatments. Follow-up tolerability was measured after each treatment by obtaining Likert scale, patient-reported, pain scores immediately after laser treatment and every six hours post-treatment, for the first 24 hours. The primary end point was tolerability and safety, defined as pain scores consistently < 4 and no deep second-degree burns during the 24-hour post-treatment period. The secondary end point was disease recurrence at one year. Twelve patients completed 5 LHD sessions and one patient completed 4. There was 100% tolerability of treatments with no occurrence of second-degree burns. No patient was unable to complete a treatment session because of discomfort. Significantly diminished hair growth was noted after 3 treatments. All 13 patients were recurrence-free at a median follow-up of 13 months post-treatment initiation. Researchers concluded that LHD is safe and well tolerated in adolescents with pilonidal disease and may be effective at decreasing pilonidal disease recurrence. A prospective RCT is planned to determine effectiveness of LHD compared with chemical/mechanical depilation methods in preventing pilonidal disease recurrence.

Khan et al. (2016) conducted a retrospective study evaluating the use of LHD for treating 19 patients with recurrent pilonidal sinus following multiple surgical treatments. Patients received outpatient long-pulsed alexandrite laser for depilation in the sinus area. There was a significant reduction in hair density after laser treatment. The disease-free period after laser treatment was significantly longer than after surgical treatment alone. 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, LHD is an efficient and cost-effective method of preventing recurrence and reducing morbidity and loss of person-hours. This study is limited by a small sample size and lack of a control group.

In a prospective RCT, Demircan et al. (2015) investigated the effects of LHD on patient satisfaction and recurrence in 60 patients who underwent pilonidal sinus surgery. Patients were divided in 2 groups of 30 patients each. Only the Karydakis flap reconstruction technique was performed in the first group. Two sessions of LHD were applied in the second group in addition to Karydakis flap reconstruction. The patients in the second group underwent LHD 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 Score, duration of patient's complaints, body mass index 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 2 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 2 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 third month postoperatively. In telephone interviews done 1 year after the surgery, recurrence was detected in 4% of the first group and in 20% of the second group. Recurrence rates were significantly higher in the second group. The authors concluded that their results show that LHD 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 LHD.

Ghnnam and Hafez (2011) conducted a prospective randomized study that compared permanent laser hair removal (LHR) following the excision of pilonidal disease with conventional methods for hair removal. Patients undergoing surgery for pilonidal disease were randomized to 2: those using LHR 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 (2 cases) mostly due to failure in maintaining hair removal and area hygiene. The authors advocate the use of LHD 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.

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 via phone 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 LHD. The investigators concluded that LHR after surgical interventions in pilonidal sinus disease decreases the risk of recurrence over the long term. This study had no control group which limits the validity of the study's conclusion (Oram et al., 2010).

Badawy and Kanawati (2009) evaluated the effectiveness of LHR in the natal cleft area on the recurrence rate of pilonidal sinus disease as an adjuvant therapy after surgical treatment. The study included 25 patients. Fifteen patients underwent LHR treatment using Nd:YAG laser after surgical treatment (patients' group) while ten subjects had surgery alone and did not undergo LHR)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 disease. The investigators concluded that LHR should be advised as an essential adjuvant treatment after surgical treatment of pilonidal sinus disease. This study is limited by a small sample size and lack of randomization.

Clinical Practice Guidelines

American Society of Colon and Rectal Surgeons (ASCRS)

The ASCRS guidelines for managing pilonidal disease state that elimination of hair from the gluteal cleft and surrounding skin, by shaving or laser epilation, may be used for both acute and chronic pilonidal disease in the absence of abscess as a primary or adjunct treatment measure. A weak recommendation was made by ASCRS for laser hair removal for treating pilonidal sinus disease based on insufficient level and quality of evidence to assess the significance or to provide a general recommendation for this approach (Johnson et al., 2019).

Italian Society of Colorectal Surgery (SICCR)

A consensus statement of the Italian society of colorectal surgery (SICCR) for the treatment and management of pilonidal disease states that current evidence of the efficacy of hair removal after pilonidal surgery is still low and needs additional studies, however, hair removal from the natal cleft may be useful as an additional treatment after excision of the pilonidal sinus. A randomized comparison between light amplification by stimulated emission of radiation (LASER) epilation and hair removal by means of a razor or depilatory creams demonstrated a lower recurrence rate if LASER was used. In hirsute patients, postoperative epilation is recommended (Milone et al., 2021).

Hypertrophic Burn Scars

In a 2022 Cochrane database systematic review, Leszczynski et al. assessed the effects of laser therapy for treating hypertrophic and keloid scars. RCTs were included if they compared laser therapy with placebo, no intervention or another intervention. The review included 15 RCTs, involving 604 adults and children. Individual sample sizes ranged from 10 to 120 participants and follow up ranged from 12 weeks to 12 months. The results showed that for fractional carbon dioxide (CO_2) laser treatment versus no treatment, very low-certainty evidence of impact on hypertrophic and keloid scar severity. For fractional CO_2 laser versus verapamil, no authors reported enough data regarding the severity of the scars to compare the interventions. Due to very low-certainty evidence, it is also uncertain whether CO_2 laser plus TAC impacts on keloid scar severity compared with cryosurgery plus intralesional corticosteroid triamcinolone acetonide (TAC). Furthermore, only very low-certainty evidence is available on treatment-related adverse effects. The authors concluded that there is insufficient evidence to support or refute the effectiveness of various laser therapies for the treatment of hypertrophic and keloid scars and further high-quality trials, with validated scales and core outcome sets should be developed.

Staubach et al. (2022) conducted a study in their institution of 77 children with scars after thermal injury. These were treated at least three times or more by CO_2 laser or in combination with pulsed dyed laser (PDL) and followed for ten years. Prior to treatment, scar texture and elasticity were objectively determined by a skin elasticity analysis system, and for the subjective evaluation, a questionnaire was given to the patients or their parents. Additional assessment tools were the Patient and Observer Scar Assessment Scale (POSAS) and Vancouver Scar Scale (VSS). The results showed a statistically significant improvement in elasticity in all scars of any age after each laser treatment. In addition, a significant correlation was found between the number of laser treatments and an increase in elasticity. The assessments of scars after one or more laser sessions by the observer as well as the patient showed a decreasing score in all categories with an increase in the number of laser therapies. The VSS score also improved significantly after each laser session. The mean score before treatment was around 7, and after the first laser session, was already below 6. Subjectively, the results showed 96% of patients or their parents

were satisfied with the laser therapy, and 90% wished to repeat the procedure. The authors concluded that this study demonstrates objective improvements in elasticity following laser treatment with no adverse effects reported. This study is limited by a small number of patients in a single institution. Furthermore, there was a lack of randomization with controls to compare the results to standards of care for scars. Additionally, treatment was combined with PDL, making it difficult to assess results of CO_2 laser treatment. Further high-quality research is needed to validate these findings.

In a 2021 systematic review, Buhalog et al. evaluated the existing literature regarding ablative fractional lasers for the treatment of hypertrophic scars. Twenty-three retrospective cohort randomized controlled trials, quasi-randomized controlled trials, observational prospective cohort, or case series with five or more subjects with hypertrophic scars incurred from burns and related trauma were included. 859 patients were included and underwent a total of 2433 laser treatments. The majority of the studies utilized the Vancouver Scar Scale (VSS) as a primary outcome measure. The Patient and Observer Scar Assessment Scale (POSAS) was the next most common. Other objective outcome measures included ultrasound for scar height/thickness, instruments to assess scar pliability and color, quartiles of overall improvement, histologic evaluation of collagen and elastin architecture and content, immunohistochemistry for growth factors and other mediators, and range of motion. Subjective outcome tools used included quality of life indices, scales of pruritus, and patient willingness to pay for treatment. The results showed that of the studies that reported the overall VSS and POSAS, there was statistically significant improvement of all outcomes measured with these tools. Furthermore, 22 of the 23 studies documented statistically significant and meaningful improvements in nearly all outcome measures. Laser treatments were well tolerated in general, with minor adverse effects such as skin discoloration, pain and swelling, blistering, erythema, infection, and ulceration typically resolved by final follow up visit. The authors concluded that ablative fractional lasers are emerging as an alternative scar management treatment between conservative measures and surgical management. Treatment is well tolerated and has a relatively low incidence of minor adverse events. Future studies should prioritize standardized protocols including assessments of function and quality of life. This study is limited by the significant heterogeneity and high risk of bias of the included studies.

In a systematic review and meta-analysis of 15 published studies to evaluate the efficacy of fractional CO_2 lasers in treating burn scars, Choi et al. (2021) reported that laser therapy alone yielded statistically significant improvements in scar profiles with few reported adverse effects. The analysis included a total of 778 patients with a median age of 22 years. All of the studies used ablative fractional CO_2 laser (AFL-CO_2) with a median of 2.5 treatments per patient over a range of 1-3 months between treatments. Indications for treatment included large, symptomatic hypertrophic scars with minimum treated areas ranging from 20 cm2 to 100 cm2. Response to therapy was measured in most of the studies with the Vancouver scar scale (VSS) (n = 12 studies) and patient/observer subjective assessment scale (POSAS) (n = 9 studies). The authors reported that patients treated with AFL-CO_2 showed meaningful, rapid improvement in burn scars as demonstrated with statistically significant improvements in validated scar scores in their analysis. The authors concluded that AFL-CO_2 laser therapy is safe and effective for the treatment of burn scars.

Issler-Fisher et al. (2021) conducted a retrospective, single-center, case-control study to look at the impact of one ablative fractional CO_2 laser (AFL-CO_2) treatment compared to conventional conservative treatment. The study included 187 patients with 167 in the AFL-CO_2 treatment group and 20 in a control cohort whose AFL-CO_2 treatment was delayed due to access to care issues. Age, gender, ethnicity, Fitzpatrick skin type, smoking status, co-morbidities, and prolonged wound healing showed no significant differences between the two study groups. The median time since injury of the two groups was 16 months and the timeframe between initial assessment and the median follow up was approximately 5 months The control cohort patients received simple, conservative care (silicone, pressure garments, etc.) and then were re-assessed prior to undergoing AFL-CO_2. The authors reported a significant reduction in scar thickness in the AFL-CO_2 group but no significant improvement in the control group and that subjective parameters had decreased significantly in the AFL-CO_2 group but had worsened at the follow-up in untreated groups. The complication rate was 2.9%. Limitations included the retrospective, single-center study design, and the risk of subjective bias due to the observational aspect of data collection tools used, The authors concluded that AFL-CO_2 was an effective and safe treatment modality for burn scars with improvement in thickness, symptoms and quality of life of burn survivors when compared to conventional scar treatment.

In 2021, Miletta et al. reported the results of a multicenter, site-controlled, prospective open-label study to determine the objective and subjective changes in mature, stable hypertrophic burn scars treated with a fractional ablative carbon dioxide (CO_2) laser, at least one year post burn injury, in 29 subjects aged 11 years and older (12 children and 10 adults). Objective and patient-reported outcome measures were documented at baseline, at each monthly laser treatment, and 6 months after treatment. Objective measurements assessed included mechanical skin torque to measure viscoelastic properties, ultrasonic imaging to measure scar thickness, and reflectometry to measure erythema and pigmentation. Subjective measures included

health-related quality of life, patient and investigator scar assessment scales, and blinded scoring of before and after photographs. Each subject received 3 monthly treatment sessions with an ablative fractionated CO_2 laser. Of the 29 participants, 26 received at least 1 fractional CO_2 laser treatment and 22 received 3 treatments. The results showed statistically significant objective improvements in elastic stretch, elastic recovery, extensibility, and thickness. Patient- and physician-reported scar appearance and pain/pruritus were also significantly improved, these improvements were sustained at 6 month follow up. The authors concluded that fractional ablative laser treatment provides significant, sustained improvement of elasticity, thickness, appearance, and symptoms of mature hypertrophic burn scars in children and adults. These including contractured scars for which patients reported increased freedom of movement. This study is limited by the small number or participants and lack of long-term follow up. Future clinical studies should address the potential combination of laser with other treatments, dose-response data, and other determinants of individual response to treatment.

Peng et al. (2021) conducted a meta-analysis of twenty articles comprised of randomized controlled trials, cohort, case-control, and comparative studies, to assess the efficacy and safety of fractional CO_2 for the treatment of burn scars. The results showed significant improvements in the VSS, as well as the patient and observer scores of the POSAS. Scar thickness as measured by ultrasound was significantly reduced, as was pigmentation, elasticity, vascularity, pliability, and height of scar. Scar firmness as measured by cutometer was however not reduced. Only 5 studies reporting adverse side effects that included hypo/hyperpigmentation, discoloration, erythema, infection, bleeding and swelling, and none were severe. The authors concluded that treatment with fractional CO_2 significantly improves the appearance and morphology of burn scars evaluated using the VSS and POSAS by both patients and the physician, as well as ultrasound evaluated scar thickness. Limitations of this study include substantial heterogeneity of the studies, which included multiple countries, range of follow up and different treatment session protocols which limit generalizability. Additionally, most of the included studies had a small number of participants. Furthermore, the influence of other variables such as burn size and severity, hypertrophic scarring, and laser delivery parameters were not assessed. Well designed, larger studies are needed to validate these findings.

Osterhoff et al. (2021) conducted a systematic review regarding the outcomes of erythema, pigmentation, height, and pliability of the different laser systems on hypertrophic scarring (HR) and keloid. Thirteen studies with 16 study arms reporting outcomes on scar characteristics were identified. Three studies reported outcomes on characteristics with CO 2 laser system in fractional setting. In erythema a mean 56% improvement was seen, above the overall mean of 37%. Regarding pigmentation, a mean reduction of 36% was reported above the overall mean of 8%. Height was improved by 46%, where the overall mean was 37%. A mean 59% improvement was reported in pliability, above the 47% overall mean. Reduced pliability corresponds with complaints of contractures, and a clinically relevant improvement was seen in most study arms, with a slight advantage to CO 2 10,600 nm laser system. This systematic review suggests that the ablative fractional laser systems (CO 2 10,600 nm and the Er:YAG 2940 nm) yielded the most improvement across all scar characteristics. Most studies scored the scars by only utilizing observed subjective clinical improvement. Future randomized controlled trials and prospective studies with a methodologically strong design, well- defined scar characteristics, standardized, and validated outcome measurements are needed to confirm this conclusion.

Zhang et al. (2019) conducted a meta-analysis to evaluate the effectiveness of fractional carbon dioxide (CO_2) laser for the treatment of burn scars. Fourteen studies were included and all except one retrospective study were prospective in design and were single arm evaluations. There was no significant publication bias identified. The results showed significant improvements in Vancouver Scar Scale (VSS), Patient and Observer Scar Assessment Scale (POSAS), and Scar Assessment Scale (SAS) scores after treatment especially with regards to pigmentation, vascularity, pliability, and height of scar. Pain and pruritis also improved with this treatment. However, scar thickness decreased statistically non-significantly and no improvement could be observed in scar firmness or elasticity, although lesser data were available to evaluate scar thickness, firmness and elasticity. This meta-analysis finds that 1 to 4 sessions of treatment of burn scars with fractional CO_2 laser is associated with significantly improved outcomes.

Patel et. al (2019, included in Buhalog and Chloi systematic reviews) conducted a prospective cohort study of pediatric burn patients undergoing carbon dioxide ablative fractional laser (CO_2-AFL) treatment of hypertrophic, symptomatic burn scars at a tertiary care regional burn center during a 2-year period. 49 patients with burn severity of full thickness (63.6%) and deep partial thickness (47.7%) were treated with a total of 180 laser sessions. Observer-rated POSAS scores revealed statistically significant improvements in pigment, thickness, relief, pliability, and surface area after one treatment with continued improvement until the last laser session. Patient-rated POSAS revealed statistically significant improvements in color, stiffness, thickness, and irregularity after laser treatments. Total POSAS improved from 89.6 ±17.5 to 76.6 ±16.8 ($p < .0001$) after one treatment with further improvement to 69.2 ±14.9 ($p < .0001$) at the final laser session. The authors concluded that CO_2-AFL therapy improves

hypertrophic burn scars on both patient- and observer-rated scales confirming statistical and clinical significance to both providers and families. These findings demonstrate that CO_2-AFL can improve hypertrophic burn scars in pediatric patients providing a lower risk alternative to invasive therapies and a more immediate, efficacious alternative to more conservative scar treatments.

In 2020, an international panel of 26 dermatologists and plastic and reconstructive surgeons from 13 different countries and a variety of practice backgrounds was self-assembled to develop evidence-based consensus recommendations regarding laser treatment for traumatic scars and contractures. They intended to highlight the potential of laser techniques and offer recommendation and promote wider patient access guided by future high-quality research. The panel recommendations for texture, pliability, thickness, and contractures state the single most effective laser type is ablative fractional laser and it is groundbreaking treatment, and one of the most important developments in scar treatment in decades, with additional research needed to determine optimal beam profile. It was concluded that lasers are a first-line therapy in the management of traumatic scars and contractures, and patients without access to these treatments may not be receiving the best available care after injury. Updated international treatment guidelines and reimbursement schemes, additional high-quality research, and patient access should reflect this status (Seago et al., 2020, included in Buhalog systematic review).

Clinical Practice Guidelines

International Society for Burn Injury (ISBI)

The 2016 practice guidelines for burn care addressed the role of lasers in the management of post burn scars. The ISBI states that the most promising results for improving texture and pliability of thick scar tissue have been shown from studies using nonablative fractional lasers.

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 study participants serve 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.

A systematic review and network meta-analysis of topical pharmacological, oral pharmacological, physical and combined treatments for acne vulgaris was conducted by Mavranezouli et al. (2022) to inform national guidance on the management of acne vulgaris for the National Institute for Health and Care Excellence (NICE). The NICE guideline is summarized below in the Clinical Practice Guidelines section. This study included 179 RCTs (112 studies related to mild-to-moderate acne and 67 studies for moderate-to-severe acne) with approximately 33,753 observations across 49 treatment classes. Topical pharmacological treatments, oral pharmacological treatments, chemical peels, combination therapies and light therapies (including photochemical therapies (blue, red or combined blue/red light), photodynamic therapy (i.e., therapy comprising a light source, e.g., red light, blue light, daylight, and a photosensitizing chemical, e.g., 5-aminolaevulinic acid, methyl aminolevulinate) and other phototherapies) were evaluated. The authors stated that the quality of the included RCTs was judged to be moderate to very low overall with 52 of the 112 RCTs for mild-to-moderate acne at high risk of bias and 36 of the 67 RCTs for moderate-to-severe acne being at high overall risk of bias. The authors reported that topical treatment combinations, chemical peels and photochemical therapy were most effective for mild-to-moderate acne when compared to placebo, The authors stated that, for moderate-to-severe acne, topical treatment combinations, oral antibiotics combined with topical treatments, oral isotretinoin and photodynamic therapy were most effective for moderate-to-severe acne. The authors concluded that further research is needed for chemical peels, photochemical and photodynamic therapies as the evidence was promising but limited.

Sapra et al. (2022) conducted a single center, retrospective chart review of 187 patients with acne vulgaris (acne) to evaluate the safety of concomitant therapy of oral isotretinoin with non-ablative laser (NAL), specifically multiplex pulsed dye laser and Nd:YAG. The average age of the participants was 21.4 years (12 – 47 years) and all participants had clinical Investigator Global Assessment (IGA) acne grading of moderate or severe facial acne with 56.1% also having acne scarring and 10.7% also having cystic acne. NAL was administered within six months after starting their isotretinoin therapy in 6.4% (n = 12) of the participants, in 53.5% (n = 100) of patients only during the usage of isotretinoin and in 40.1% (n = 75) both during and after isotretinoin usage. The authors reported that 31.6% of participants experienced mild side effects while on concomitant isotretinoin and NAL therapy. Of those with available effectiveness data, 99.2 percent of patients (n = 132) achieved an IGA score of clear or almost clear, which was maintained up until the most recent follow-up. The mean length of follow-up was 902.7 days, with a

minimum of 63 and a maximum of 3520 days. Limitations of the study included the single-center, retrospective design, the lack of standardized lesion count assessments, and the lack of a control group. The authors concluded that their study demonstrated the safety of performing NAL therapies during and immediately after isotretinoin use.

A prospective study by Piccolo et al. (2022) was performed to assess the efficacy, safety, and reproducibility of a novel intense pulsed light (IPL) protocol as a monotherapy in the treatment of acne of the chest and back. A total of 50 patients ranging from 18 to 40 years of age (mean age 23.8 years old) with Fitzpatrick Skin Types II to III and moderate papulopustular acne on chest and back were retrospectively enrolled from the authors' private practice centers. Four IPL sessions at two-week intervals on each patient was performed. Per the authors, excellent outcome was achieved in 50 percent of the patients and a good outcome in the 35 percent of the patients. Patients experienced light erythema and mild burning as the most common side effects, which spontaneously resolved within 24 to 96 hours. The authors concluded that the study demonstrated IPL to be a safe and effective treatment for severe cases of acne on the chest and back, providing good aesthetic and therapeutic results in 85 percent of treated patients. Further research with randomized controlled trials is needed to validate these findings.

In a Clinical Evidence Assessment of photodynamic therapy (PDT) for benign skin lesions, ECRI (2021) evaluated the application of PDT for treatment of acne vulgaris, psoriasis, sebaceous gland hyperplasia and refractory nongenital warts. Their review of PDT for acne vulgaris comprised of a review of one published systematic review with meta-analysis of thirteen RCTs. ECRI's stated that the meta-analysis showed PDT improved inflammatory acne with a mean percentage reduction in the inflammatory lesion count and total effective response; however, ECRI noted the evidence was limited by great heterogeneity across studies and the variability in PDT methods including different light sources and wavelengths. According to the ECRI assessment, these limitations affect the generalizability of the conclusions that can be drawn regarding the use of PDT for treating acne vulgaris.

In a meta-analysis, Lu et al. assessed the safety and efficiency of intense pulse light (IPL) therapy in the treatment of acne vulgaris. The authors reviewed eight RCTs, including the El-Latif (2014), the Liu (2014a) and the Mohamed (2016) studies cited below. Three of the eight trials applied IPL in combination with other therapies, while others performed IPL alone. The course of treatment varied from 1 to 3 months, and the follow-up period was between 3 weeks and 3 months in those trials that reported the length of follow-up. The meta-analysis included a total of 450 participants and concluded that IPL is not as efficient as other supplementary therapies as the results of the IPL group's mean percentage reduction of inflammatory acne lesions (MPRI) was poorer than that of the control group that was treated with pulsed dye therapy and that the efficiency of IPL was poor among African and Asian populations. They also found that the difference in efficiency between IPL and 1064 nm Nd:YAG was not statistically significant. The authors noted that there are limitations to the meta-analysis, including the heterogeneities among the studies including the use of various filters for the IPL system, various pulse modes, number of treatment sessions and the interval period. Other limitations they identified include a lack of studies with large sample size, and that all the studies include in the meta-analysis were single-center.

Scott et al. (2019) performed a systematic review and meta-analysis of studies assessing the effectiveness of blue-light therapy for acne. Fourteen trials (n = 698) were included. Only three of the trials reported significant improvements in investigator-assessed acne severity with blue light therapy over a control group. Patient-assessed improvements were reported in two studies that favored blue light. Mean difference in the mean number of noninflammatory (open and closed comedones) and inflammatory lesions (papules, pustules, nodules) was nonsignificant between the groups at several time points and overall. Adverse events were generally mild and favored blue light or did not significantly differ between groups. Methodological and reporting limitations of existing evidence limit conclusions about the effectiveness of blue light for acne. Limitations included small sample sizes, short intervention periods, and high risk of bias.

In a systematic review, de Vries et al. (2018) assessed the efficacy and safety of non-pharmacological therapies in the treatment of acne vulgaris (AV). 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 IPL (400-700 and 870-1200 nm) and the diode laser (1450 nm). Initially, conflicting evidence was found for PDL (585-595 nm). Circumstantial evidence was the basis for non-pharmacological therapies in the treatment of AV, for which the authors were unable to draw clear conclusions. They concluded that these outcomes provide a first step in future research.

Boen et al. (2017) performed a systematic review of the literature for PDT used for acne and critically evaluated the studies. Sixty-nine clinical trials, 4 case reports, and 2 retrospective studies met the inclusion criteria. Seven of the studies were high

quality. The most common photosensitizers used were 5-ALA and MAL, and both showed similar response. Red light was the most frequently used light source, followed by IPL, and showed comparable results. Inflammatory and non-inflammatory lesions both responded to treatment, with inflammatory lesions showing greater clearance in most studies. AEs 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.

A Cochrane review conducted by Barbaric et al. (2016) evaluated the effects of light treatment of different wavelengths for acne. Seventy-one RCTs (4211 participants, median sample size 31) were included in the review. Light interventions differed greatly in wavelength, dose, active substances used in 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 most 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) 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 quality of evidence) 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 PDL 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 8 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 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 RCTs and 1 was retrospective study. The authors concluded that 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.

Antoniou et al. (2016) conducted a 12-week multicenter, split-face RCT 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 ac. 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 3 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 AEs. 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 AEs and no patient discontinuation from the study from any AE. 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 most 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 Nd:YAG in treatment of facial AV. Seventy-four patients were enrolled in this prospective, split-face, RCT. 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 AV. Study limitations include the absence of an established standard therapy as a control group.

In a systematic review, Wat et al. (2014) reviewed the evidence to provide recommendations to guide physicians in the application of 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 AV. 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 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.

In an evidence-based review, Zheng et al. (2014) assessed the effects and safety of PDT for acne. A total of 14 RCTs involving 492 patients were included. Photosensitizers included ALA, MAL, and indole-3-acetic acid (IAA). Light sources included red light, PDL, 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.

Erceg et al. (2013) systematically reviewed the literature concerning PDL treatment for inflammatory skin diseases including AV. The authors concluded that PDL treatment can be recommended as an effective and safe treatment for AV (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 RCTs.

El-Latif et al. (2013) compared the clinical efficacy of IPL therapy 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 2 groups. The first group was treated by BP while the second group was treated by IPL. Treatment with both BP 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.

Karsai et al. (2010) assessed the efficacy of adjuvant PDL treatment when combined with a proven topical treatment (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 AC.

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., 2014a; Song et al., 2014; Moneib et al., 2014).

Clinical Practice Guidelines

National Institute for Health and Care Excellence (NICE)

The National Institute for Health and Care Excellence (NICE, NG198) made a "consider recommendation" only for photodynamic therapy for people aged 18 and over with moderate to severe acne if other treatments are ineffective, not tolerated, or contraindicated. This recommendation was based on evidence from small studies showing therapy from these light sources with or without adding chemical or physical photosensitizer may be effective. NICE did not make a strong recommendation due to the limited evidence when compared with pharmacological treatments. No recommendation was made for any other form of light therapy based on the committee's conclusion that the overall quality of studies was very low with a serious risk of bias and risk of very serious imprecision. The committee stated further research is required to determine the most effective physical treatments for acne (NICE, 2021, updated 2023).

American Academy of Dermatology (AAD)

In a guideline of care for the management of AV, the AAD states that there is limited evidence to recommend the use and benefit of physical modalities for the routine treatment of acne, including PDL. According to the AAD, large, prospective, multicenter, randomized, double-blinded controlled trials comparing light and laser devices to placebo are needed. The 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).

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. Additional research is needed to determine efficacy and safety and to clarify patient selection and treatment parameters.

In a single-center, single-blind RCT to compare the effectiveness of long-pulsed alexandrite laser (LPAL) with that of pulsed-dye laser (PDL) for rosacea, Park et al. (2022) recruited 27 patients who were clinically diagnosed with erythematotelangiectatic or PP rosacea; however, only 23 patients completed the study. The age range of the participants was 21 to 64 years (mean age 41.5 years) and 78.3% (n = 18) were female. Each patient received a total of 4 monthly treatments with follow-up sessions at 1 month (visit 5, short-term) and 3 months (visit 6, long-term) after the last treatment. The participants were randomly assigned split face and received LPAL plus low-fluence Nd:YAG on one side of their face and PDL on the contralateral side of their face. The erythema index (EI) was measured at every visit with skin analysis systems, and two independent dermatologists evaluated digital photographs for five-point global aesthetic improvement scale (GAIS). The authors reported that the EI significantly decreased on both treated sides at their one-month (5^{th} visit) evaluation and that three months after the 4^{th} treatment (on their 6^{th} visit), the reduction in the EI was well maintained on both sides. When the authors compared the improvement in EI between the two groups, the percentage reduction in the EI on the LPAL-treated side was not inferior to the PDL-treated side through the 6^{th} visit. They also reported that the GAIS and patient satisfaction were comparable between LPAL and PDL sides and did not show any significant difference. Limitations of the study include the small size of the participant population, the single-center design, the uncertainty around how much each wavelength contributed to reducing the erythema in rosacea with the use of the dual-wavelength laser device. The authors concluded that the study showed that the decrease in EI in the treatment of rosacea was comparable between PDL and LPAL and that LPAL could be a promising alternative treatment option for rosacea.

Badawi et al (2020) conducted a study to evaluate the efficacy and safety of fractional ablative 2940 nm Er:YAG laser. The study included 16 patients with a mean age of 57.8 years who had mild to moderate rhinophyma for two to 15 years. Only one patient

experienced a recurrence of the condition in the 6-month follow-up period. The authors concluded that the use of Er:YAG laser in this study demonstrated efficacy of the tool for treatment of mild to moderate rhinophyma with a rapid and pain-free recovery period. They noted that the study was limited by the lack of histopathological examination to rule out coexisting pathology and to demonstrate histopathological improvement of the treated area. They concluded that further research is needed to confirm their findings and to optimize laser settings and number of treatment sessions.

Zhao et al. (2020) performed a retrospective study to investigate the efficacy of dye pulsed light (DPL) treatment for erythematotelangiectatic rosacea (ETR) and determine the factors affecting that efficacy. Sixty-five patients with ETR underwent three treatment sessions with DPL at 4-week intervals and were followed up at 4 weeks after the last treatment session. Skin type, sex, age, lesion site, severity of erythema and telangiectasia, VISIA 6.0 Complexion Analysis System (Canfield Scientific, Inc., Fairfield, NJ, USA) percentile ranking, clinical photographs and red area images were recorded at baseline. The post-treatment erythematous and telangiectatic scores and VISIA percentile rankings were recorded, and the effects of different personal and clinical factors on the efficacy were statistically analyzed. The erythema and telangiectasia scores and VISIA percentile rankings showed improvement after the DPL procedures ($p < 0.01$). Regarding erythema, treatment efficacy was not affected by any of the investigated variables, including pre-treatment erythema scores, skin type, pre-treatment VISIA percentile ranking, sex, age and lesion site ($p > 0.05$). Regarding telangiectasia, the treatment efficacy was greater for mild telangiectasia than for severe telangiectasia (odds ratio = 4.14, $p < 0.05$). There was no significant difference in treatment efficacy between the moderate and severe categories (odds ratio = 4.00, $p > 0.05$). The authors concluded that DPL is not an optimal procedure for treating severe telangiectasia in patients with ETR, whereas the efficacy of the treatment for erythema was not affected by the severity of the condition. Limitations include a small sample size which makes it difficult to decide whether these conclusions can be generalized to a larger population. In addition, limited subjective and objective variables were examined, and other variables, such as disease duration, the patient's Global Improvement Assessment and Global Flushing Severity Score, were not investigated. Also, the study was retrospective and non-randomized. Further prospective research with randomized controlled trials is needed to validate these findings.

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.

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 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 AEs 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 AEs 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 2 devices, there is no way to be 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.

A Cochrane review on interventions for rosacea (van Zuuren et al., 2015) found that PDL was more effective than Nd:YAG laser based on 1 study, and it appeared to be as effective as IPL therapy (both low quality evidence). The authors stated that there was low quality evidence for laser and IPL therapy for ocular rosacea.

In a systematic review, Wat et al. (2014) reviewed the evidence to provide recommendations to guide physicians in the application of 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 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 PDL treatment for inflammatory skin diseases including rosacea. The authors noted that most conclusions formulated are not based on RCTs. The authors concluded that there is low level evidence for PDL treatment for papulopustular rosacea.

In a split-face, double-blind RCT, Alam et al. (2013) compared the effectiveness of microsecond 1064-nm Nd:YAG laser with non-purpuragenic 595-nm PDL for diffuse facial erythema or erythematotelangiectatic rosacea (ETR). 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.

Lazzeri et al. (2013) reviewed the long-term results of 67 patients affected by rhinophyma treated with 2 different methods. Forty-five patients were treated with tangential excision and 22 with a CO_2 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 CO_2 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.

Several published studies reported that light and laser therapy may be safe and effective for treating rosacea (Kim et al., 2017; Micali et al., 2018; Liu et al., 2014b) and rhinophyma (Bassi et al., 2016). Studies were limited by small sample size and study design.

Clinical Practice Guidelines

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)

In their update on the management of rosacea, the AARS issued consensus recommendations on the management of rosacea that state that laser systems, such as intense pulsed light (IPL), potassium titanyl phosphate (KTP) crystal laser, or pulsed-dye laser (PDL) devices can be used to effectively treat persistent central facial erythema without papulopustular (PP) lesions based on their systematic review and meta-analysis of lower-quality clinical trials or studies with limitations and inconsistent findings. The authors considered the benefit of device treatment for rosacea in that the therapeutic effects are generally seen over a limited number of treatment sessions, which contrast with the need for daily treatment over long periods of time with topical or oral medication. They noted that, once an endpoint of an acceptable therapeutic effect is achieved, the results are often maintained for several years. Concurrent medical therapy is frequently used to complement device treatments. The authors stated that more data are needed on optimal use of specific devices and topical alpha-agonist therapy in combination.

For granulomatous rosacea, IPL and PDL gave a lower recommendation based on the authors' review of limited trial data, usual practice patterns, expert opinion and case series. They noted there is no current standard of treatment for use of IPL or PDL in this scenario.

The consensus recommendations made by AARS for treatment of phymatous rosacea includes a low recommendation for surgical therapy for fully developed phymatous changed including carbon dioxide laser and erbium-doped yttrium aluminum garnet (YAG) laser. This recommendation was made by the committee based on usual practice, expert opinion and case series with limited trial data. (Delroso et al., 2020).

National Rosacea Society (NRS)

The National Rosacea Society (NRS) developed a consensus document on management options for rosacea that includes an updated classification system based on phenotypes. The document addresses pulsed-dye laser and intense pulsed light therapies as established practice in removing telangiectasia and diminishing erythema; however, the NRS acknowledges the lack of quality clinical evidence to support these therapies and assigns a weak rating (Thiboutot et al., 2020).

U.S. Food and Drug Administration (FDA)

This section is to be used for informational purposes only. FDA approval alone is not a basis for coverage.

Phototherapy

Several hundred different phototherapy devices have been approved by the FDA through the 510K premarket approval process. These include devices that deliver blue, green, and yellow light phototherapy; photothermolysis devices, intense pulsed dye lasers, and near-infrared lasers. Refer to the following website for more information (use product codes FTC or GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 14, 2023)

Photodynamic Therapy

A number of different photodynamic therapy devices have been approved by the FDA through their premarket approval process. Refer to the following website for more information (use product code MVF): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed June 14, 2023)

Pulsed Dye Laser (PDL)

PDLs are classified as Class II devices. In 1986, the Candela Corporation manufactured the first PDL approved by the FDA through the 510K premarket approval process for the treatment of cutaneous vascular lesions. Since then, various models have been developed and deemed substantially equivalent by the FDA. Refer to the following website for more information (use product code GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 14, 2023)

Laser Therapy

Several flashlamp-pumped pulsed dye lasers (FLDPLs), Xenon-chloride (XeCl) excimer lasers, neodymium-doped yttrium aluminium garnet (ND:YAG) and erbium:yttrium-aluminum-garnet (Er:YAG) lasers have received FDA approval. Refer to the following website for more information (use product code GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 14, 2022)

References

Alam M, Voravutinon N, Warycha M, et al. Comparative effectiveness of nonpurpuragenic 595-nm pulsed dye laser and microsecond 1064-nm neodymium:yttrium-aluminum-garnet laser for treatment of diffuse facial erythema: A double-blind randomized controlled trial. J Am Acad Dermatol. 2013 Sep;69(3):438-43.

Antoniou C, Dessinioti C, Sotiriadis D, et al. A multicenter, randomized, split-face clinical trial evaluating the efficacy and safety of chromophore gel-assisted blue light phototherapy for the treatment of acne. Int J Dermatol. 2016 Dec;55(12):1321-1328.

Ash C, Harrison A, Drew S, et al. A randomized controlled study for the treatment of acne vulgaris using high-intensity 414 nm solid state diode arrays. J Cosmet Laser Ther. 2015;17(4):170-6.

Badawi A, Osman M, Kassab A. Novel management of rhinophyma by patterned ablative 2940nm erbium:YAG Laser. Clin Cosmet Investig Dermatol. 2020 Dec 11;13:949-955.

Badawy EA, Kanawati MN. Effect of hair removal by Nd:YAG laser on the recurrence of pilonidal sinus. J Eur Acad Dermatol Venereol. 2009 Aug;23(8):883-6.

Barbaric J, Abbott R, Posadzki P, et al. Light therapies for acne. Cochrane Database Syst Rev. 2016 Sep 27;9:CD007917.

Bassi A, Campolmi P, Dindelli M, et al. Laser surgery in rhinophyma. G Ital Dermatol Venereol. 2016 Feb;151(1):9-16.

Boen M, Brownell J, Patel P, et al. The role of photodynamic therapy in acne: an evidence-based review. Am J Clin Dermatol. 2017 Mar 8.

Buhalog B, Moustafa F, Arkin L, et al. Ablative fractional laser treatment of hypertrophic burn and traumatic scars: a systematic review of the literature. Arch Dermatol Res. 2021 Jul;313(5):301-317.

Check NM, Wynne NK, Mooney DP. Resolution of mild pilonidal disease in adolescents without resection. J Am Coll Surg. 2022 Nov 1;235(5):773-776.

Chen W, Liu S, Yang C, et al. Clinical efficacy of the 595 nm pulsed dye laser in the treatment of childhood superficial hemangioma - analysis of 10-year application in Chinese patients. J Dermatolog Treat. 2015 Feb;26(1):54-8.

Chinnadurai S, Snyder K, Sathe N, et al. Diagnosis and management of infantile hemangioma. Comparative Effectiveness Review No. 168. (Prepared by the Vanderbilt University Evidence-based Practice Center under Contract No. 290-2010-0009-I.) AHRQ Publication No.16-EHC002-EF. Rockville, MD: Agency for Healthcare Research and Quality; January 2016a.

Chinnadurai S, Sathe NA, Surawicz T. Laser treatment of infantile hemangioma: A systematic review. Lasers Surg Med. 2016b Mar;48(3):221-33.

Cox C, Bettiol P, Le A, et al. CO2 laser resurfacing for burn and traumatic scars of the hand and upper extremity. Scars Burn Heal. 2022 Jan 5; 8:20595131211047694.

Demircan F, Akbulut S, Yavuz R, et al. The effect of laser epilation on recurrence and satisfaction in patients with sacrococcygeal pilonidal disease: a prospective randomized controlled trial. Int J Clin Exp Med. 2015 Feb 15;8(2):2929-33.

de Vries FMC, Meulendijks AM, Driessen RJB, et al. The efficacy and safety of non-pharmacological therapies for the treatment of acne vulgaris: A systematic review and best-evidence synthesis. J Eur Acad Dermatol Venereol. 2018 Jul;32(7):1195-1203.

Del Rosso JQ, Tanghetti E, Webster G, et al. Update on the management of rosacea from the American Acne & Rosacea Society (AARS). J Clin Aesthet Dermatol. 2020 Jun;13(6 Suppl):S17-S24.

ECRI Institute. Clinical Evidence Assessment. Photodynamic therapy for benign skin conditions. Plymouth Meeting (PA): ECRI; 2021 Jun.

El-Latif AA, Hassan FA, Elshahed AR, et al. Intense pulsed light versus benzoyl peroxide 5 % gel in treatment of acne vulgaris. Lasers Med Sci. 2013 Oct 10.

Erceg A, de Jong EM, van de Kerkhof PC, et al. The efficacy of pulsed dye laser treatment for inflammatory skin diseases: a systematic review. J Am Acad Dermatol. 2013 Oct;69(4):609-615.e8.

Faurschou A, Togsverd-Bo K, Zachariae C, et al. Pulsed dye laser vs. intense pulsed light for port-wine stains: a randomized side-by-side trial with blinded response evaluation. Br J Dermatol. 2009 Feb;160(2):359-64.

Ghnnam WM, Hafez DM. Laser hair removal as adjunct to surgery for pilonidal sinus: our initial experience. J Cutan Aesthet Surg. 2011 Sep;4(3):192-5.

Halleran DR, Onwuka AJ, Lawrence AE, et al. Laser hair depilation in the treatment of pilonidal disease: a systematic review. Surg Infect (Larchmt). 2018 Aug/Sep;19(6):566-572.

Hayes, Inc. Hayes Comparative effectiveness review of laser and light therapies for rosacea. Lansdale, PA: Hayes, Inc.; January 2018. Updated May 2020; archived February 2023.

Hivnor C, et al. Fractional ablative laser therapy is an effective treatment for hypertrophic burn scars: a prospective study of objective and subjective outcomes. Ann Surg. 2021 Dec 1;274(6): e574-e580.

International Society for Burn Injury (ISBI). ISBI practice guidelines for burn care. ISBI Practice Guidelines Committee. 2016.

Johnson EK, Vogel JD, Cowan ML, et al.; Clinical Practice Guidelines Committee of the American Society of Colon and Rectal Surgeons. The American Society of Colon and Rectal Surgeons' clinical practice guidelines for the management of pilonidal disease. Dis Colon Rectum. 2019 Feb;62(2):146-157.

Karsai S, Schmitt L, Raulin C. The pulsed-dye laser as an adjuvant treatment modality in acne vulgaris: a randomized controlled single-blinded trial. Br J Dermatol. 2010 Aug;163(2):395-401.

Keyal U, Bhatta AK, Wang XL. Photodynamic therapy for the treatment of different severity of acne: A systematic review. Photodiagnosis Photodyn Ther. 2016 Jun;14:191-9.

Khan MA, Javed AA, Govindan KS, et al. Control of hair growth using long-pulsed alexandrite laser is an efficient and cost-effective therapy for patients suffering from recurrent pilonidal disease. Lasers Med Sci. 2016 Jul;31(5):857-62.

Kim SJ, Lee Y, Seo YJ, et al. Efficacy of radiofrequency and pulsed dye laser in the treatment of rosacea. Dermatol Surg. 2017 Feb;43(2):204-209.

Krowchuk DP, Frieden IJ, Mancini AJ, et al.; Subcommittee on the Management of Infantile Hemangiomas. Clinical practice guideline for the management of infantile hemangiomas. Pediatrics. 2019 Jan;143(1):e20183475.

Lazzeri D, Larcher L, Huemer GM, et al. Surgical correction of rhinophyma: comparison of two methods in a 15-year-long experience. J Craniomaxillofac Surg. 2013 Jul;41(5):429-36.

Leszczynski R, da Silva CA, Pinto ACPN, et al. Laser therapy for treating hypertrophic and keloid scars. Cochrane Database Syst Rev. 2022 Sep 26;9(9):CD011642.

Liu J, Liu J, Ren Y, et al. Comparative efficacy of intense pulsed light for different erythema associated with rosacea. J Cosmet Laser Ther. 2014b Dec;16(6):324-7.

Liu LH, Fan X, An YX, et al. Randomized trial of three phototherapy methods for the treatment of acne vulgaris in Chinese patients. Photodermatol Photoimmunol Photomed. 2014a Oct;30(5):246-53.

Lopez JJ, Cooper JN, Fischer BA, et al. Safety and tolerability of laser hair depilation in pilonidal disease: a pilot study. Surg Infect (Larchmt). 2017 Nov/Dec;18(8):890-893.

Mavranezouli I, Daly CH, Welton NJ, et al. A systematic review and network meta-analysis of topical pharmacological, oral pharmacological, physical and combined treatments for acne vulgaris. Br J Dermatol. 2022 Nov;187(5):639-649.

Micali G, Dall'Oglio F, Verzì AE, et al. Treatment of erythemato-telangiectatic rosacea with brimonidine alone or combined with vascular laser based on preliminary instrumental evaluation of the vascular component. Lasers Med Sci. 2018 Aug;33(6):1397-1400.

Miletta N, Siwy K, Hivnor C, et al. Fractional ablative laser therapy is an effective treatment for hypertrophic burn scars: a prospective study of objective and subjective Outcomes. Ann Surg. 2021 Dec 1;274(6): e574-e580.

Milone M, Basso L, Manigrasso M, et al. Consensus statement of the Italian society of colorectal surgery (SICCR): management and treatment of pilonidal disease. Tech Coloproctol. 2021 Dec;25(12):1269-1280.

Moftah NH, Ibrahim SM, Wahba NH. Intense pulsed light versus photodynamic therapy using liposomal methylene blue gel for the treatment of truncal acne vulgaris: a comparative randomized split body study. Arch Dermatol Res. 2016 Mar 18.

Mohamed EE, Tawfik K, Elsaie M. Intense pulsed light versus 1,064 long-pulsed neodymium: yttrium-aluminum- garnet laser in the treatment of facial acne vulgaris. J Clin Diagn Res. 2016 Jul;10(7):WC01-3.

Moneib H, Tawfik AA, Youssef SS, et al. Randomized split-face controlled study to evaluate 1550-nm fractionated erbium glass laser for treatment of acne vulgaris–an image analysis evaluation. Dermatol Surg. 2014 Nov;40(11):1191-200.

National Institute for Health and Care Excellence (NICE). [NG198] Acne vulgaris: management. June 2021, updated May 2023.

Nikolis A, Fauverghe S, Scapagnini G, et al. An extension of a multicenter, randomized, split-face clinical trial evaluating the efficacy and safety of chromophore gel-assisted blue light phototherapy for the treatment of acne. Int J Dermatol. 2018 Jan;57(1):94-103.

Oge LK, Muncie HL, Phillips-Savoy AR. Rosacea: diagnosis and treatment. Am Fam Physician. 2015 Aug 1;92(3):187-196.

Oosterhoff TCH, Beekman VK, van der List JP, et al. Laser treatment of specific scar characteristics in hypertrophic scars and keloid: A systematic review. J Plast Reconstr Aesthet Surg. 2021 Jan;74(1):48-64.

Oram Y, Kahraman F, Karincaoğlu Y, et al. Evaluation of 60 patients with pilonidal sinus treated with laser epilation after surgery. Dermatol Surg. 2010;36(1):88-91.

Pariser DM, Eichenfield LF, Bukhalo M, et al. Photodynamic therapy with 80 mg/g methyl aminolaevulinate for severe facial acne vulgaris: a randomised vehicle-controlled study. Br J Dermatol. 2015 Dec 13.

Park S, Lee JH, Kang E, et al. A randomized split-face comparative study of long-pulsed alexandrite plus low-fluence Nd:YAG laser versus pulsed-dye laser in the treatment of rosacea. Lasers Surg Med. 2022 Nov;54(9):1217-1225.

Patel SP, Nguyen HV, Mannschreck D, et al. Fractional CO_2 laser treatment outcomes for pediatric hypertrophic burn scars. J Burn Care Res. 2019 Jun 21;40(4):386-391.

Peng W, Zhang X, Kong X, et al. The efficacy and safety of fractional CO_2 laser therapy in the treatment of burn scars: A meta-analysis. Burns. 2021 Nov;47(7):1469-1477.

Pronk AA, Eppink L, Smakman N, et al. The effect of hair removal after surgery for sacrococcygeal pilonidal sinus disease: a systematic review of the literature. Tech Coloproctol. 2018 Jan;22(1):7-14.

Romic I, Augustin G, Bogdanic B, Bruketa T, Moric T. Laser treatment of pilonidal disease: a systematic review. Lasers Med Sci. 2022 Mar;37(2):723-732.

Salimi-Jazi F, Abrajano C, Yousefi R, et al. Increasing amount of hair reduction using laser correlates with lower probability of recurrence in patients with pilonidal disease. J Pediatr Surg. 2023 Feb 25:S0022-3468(23)00174-4.

Sapra S, Lultschik SD, Tran JV, Dong K. Concomitant therapy of oral isotretinoin with multiplex pulsed dye laser and Nd: YAG laser for acne. J Clin Aesthet Dermatol. 2022 Sep;15(9):20-24.

Scott AM, Stehlik P, Clark J, et al. Blue-light therapy for acne vulgaris: a systematic review and meta-analysis. Ann Fam Med. 2019 Nov;17(6):545-553.

Seago M, Shumaker PR, Spring LK, et al. laser treatment of traumatic scars and contractures: 2020 International Consensus Recommendations. Lasers Surg Med. 2020 Feb;52(2):96-116.

Seo HM, Kim JI, Kim HS, et al. Prospective comparison of dual wavelength long-pulsed 755-nm alexandrite/1,064-nm neodymium:yttrium-aluminum-garnet laser versus 585-nm pulsed dye laser treatment for rosacea. Ann Dermatol. 2016 Oct;28(5):607-614.

Shen L, Zhou G, Zhao J, et al. Pulsed dye laser therapy for infantile hemangiomas: a systemic review and meta-analysis. QJM. 2015 Jun;108(6):473-80.

Song BH, Lee DH, Kim BC, et al. Photodynamic therapy using chlorophyll-a in the treatment of acne vulgaris: a randomized, single-blind, split-face study. J Am Acad Dermatol. 2014 Oct;71(4):764-71.

Staubach R, Glosse H, Fennell S et al. A single-Institution experience about 10 years with children undergoing fractional ablative carbon dioxide laser treatment after burns: measurement of air pressure-induced skin elevation and retraction time (Dermalab) including standardized subjective and objective scar evaluation. J Burn Care Res. 2022 Sep 26.

Steele SR, Perry WB, Mills S, et al. Standards Practice Task Force of the American Society of Colon and Rectal Surgeons. Practice parameters for the management of pilonidal disease. Dis Colon Rectum. 2013;56(9):1021-1027.

Thiboutot D, Anderson R, Cook-Bolden F, et al. Standard management options for rosacea: the 2019 update by the National Rosacea Society Expert Committee. J Am Acad Dermatol. 2020 Jun;82(6):1501-1510.

van Zuuren EJ, Fedorowicz Z, Carter B, et al. Interventions for rosacea. Cochrane Database Syst Rev. 2015 Apr 28;4:CD003262.

van Zuuren EJ. Rosacea. N Engl J Med 2017; 377:1754-1764.

Voravutinon N, Rojanamatin J, Sadhwani D, et al. A comparative split-face study using different mild purpuric and subpurpuric fluence level of 595-nm pulsed-dye laser for treatment of moderate to severe acne vulgaris. Dermatol Surg. 2016 Mar;42(3):403-9.

Wang L, Li L, Huang C. Efficacy of photodynamic therapy in the treatment of port wine stains: A systematic review and meta-analysis. Front Med (Lausanne). 2023 Feb 21;10:1111234.

Wat H, Wu DC, Rao J, et al. Application of intense pulsed light in the treatment of dermatologic disease: a systematic review. Dermatol Surg. 2014 Apr;40(4):359-77.

Yazdi A, Lyons CW, Roberts N. Visually augmented targeted combination light therapy for acne vulgaris: a case report. J Med Case Rep. 2017 Oct 31;11(1):316.

Zaenglein AL, Pathy AL, Schlosser BJ, et al. Guidelines of care for the management of acne vulgaris. J Am Acad Dermatol. 2016 Feb 15.

Zhang C, Yin K, Shen YM. Efficacy of fractional carbon dioxide laser therapy for burn scars: a meta-analysis. J Dermatolog Treat. 2019 Dec 22:1-6.

Zheng W, Wu Y, Xu X, et al. Evidence-based review of photodynamic therapy in the treatment of acne. Eur J Dermatol. 2014 Jul-Aug;24(4):444-56.

Policy History/Revision Information

Date	Summary of Changes

04/01/2024	**Related Policies**
	• Added reference link to the Medical Policy titled *Outpatient Surgical Procedures – Site of Service (for Tennessee Only)*
	Coverage Rationale
	• Replaced language indicating "pulsed dye laser therapy is proven and medically necessary for treating cutaneous hemangiomata" with "pulsed dye laser therapy is proven and medically necessary for treating cutaneous *hemangioma/* hemangiomata"
	• Changed coverage status for laser hair removal for the treatment of pilonidal sinus disease from "unproven and not medically necessary" to "proven and medically necessary when [the listed] criteria are met"
	  ○ Added language to indicate laser hair removal is proven and medically necessary for the treatment of pilonidal sinus disease that has been or is being treated with surgery performed to debride an accumulation of fluid or pus causing the formation of a cyst or abscess
	  ○ Removed language indicating laser hair removal is unproven and not medically necessary for treating pilonidal sinus disease due to insufficient evidence of efficacy
	• Added language to indicate fractional ablative laser fenestration [e.g., carbon dioxide (CO_2) laser, Erbium Yttrium Aluminum Garnet (Er:YAG) laser] of hypertrophic burn scars is proven and medically necessary when **both** of the following criteria are met:
	  ○ The burn scar is causing functional impairment (i.e., limiting range of motion) and the treatment can be reasonably expected to improve the functional impairment
	  ○ The individual has tried and failed at least one conventional treatment (e.g., hypoallergenic paper tape, pressure garments, or silicone kits with gel/sheeting)
	• Revised list of light and laser therapies that are unproven and not medically necessary for treating rosacea, rhinophyma, and acne vulgaris; added:
	  ○ Neodymium: Yttrium-Aluminum-Garnet (Nd:YAG)
	  ○ Excimer
	Applicable Codes
	Hypertrophic Burn Scars
	• Added CPT codes 0479T, 0480T, and 17999
	• Added ICD-10 diagnosis codes L91.0 and L90.5
	Laser Hair Removal
	• Added ICD-10 diagnosis codes L05.01, L05.02, L05.91, and L05.92
	Supporting Information
	• Updated *Description of Services*, *Clinical Evidence*, *FDA*, and *References* sections to reflect the most current information
	• Archived previous policy version CS069TN.O

Instructions for Use

This Medical Policy provides assistance in interpreting UnitedHealthcare standard benefit plans. When deciding coverage, the federal, state or contractual requirements for benefit plan coverage must be referenced as the terms of the federal, state or contractual requirements for benefit plan coverage may differ from the standard benefit plan. In the event of a conflict, the federal, state or contractual requirements for benefit plan coverage govern. Before using this policy, please check the federal, state or contractual requirements for benefit plan coverage. 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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