Light and Laser Therapy (for Nebraska Only)

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➲ Instructions for Use

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Related Policy

- Cosmetic and Reconstructive Procedures (for Nebraska Only)

Application

This Medical Policy only applies to the State of Nebraska.

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 for control of hair regrowth.

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:

- Acne vulgaris
- Onychomycosis
- Rhinophyma
- Rosacea

Excimer laser therapy is considered cosmetic and not medically necessary for treatment of vitiligo.

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

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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 code 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
Excimer Laser Therapy	
96999	Unlisted special dermatological service or procedure
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	
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue

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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	
L90.5	Scar conditions and fibrosis of skin
L91.0	Hypertrophic scar
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

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

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(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.

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.

Onychomycosis

Onychomycosis (OM) is a persistent nail fungus infection that affects the nail bed and plate and leads to thickened, brittle nails. While it can occur in both finger and toenails, OM of the toenail is much more common. Current conventional treatment includes topical and/or systemic antifungal agents with systemic antifungals being most effective. However, mixed efficacy is noted with topical antifungals due to the need for long-term therapy and lower therapeutic concentrations while systemic antifungals are reported to have higher rates of complications. The use of laser therapy, either independently of or in conjunction with topical therapy, has been proposed as an alternative treatment modality (Bodman et al., 2024).

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).

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.

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.

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Vitiligo

Vitiligo is a chronic skin disorder characterized by the loss of melanocytes in the skin resulting in the appearance of white, irregularly shaped patches of skin that enlarge over time. The cause of vitiligo is believed to involve a combination of genetic, autoimmune, and environmental factors across all ages, races and sexes. While vitiligo does not pose any direct health risks, it may lead to psychological stress due to its cosmetic effects and associated social stigma. There are several treatment options available for re-pigmentation such as topical corticosteroids, calcineurin inhibitors, phototherapy, excimer laser therapy (ELT), microskin grafting, and/or cosmetic camouflage (Hayes, 2023).

Clinical Evidence

Port-Wine Stains (PWS) and Hemangiomata

In a systematic review and meta-analysis evaluating the safety of pulsed dye laser (PDL) therapy for treating PWS, Shi et al. (2023) reviewed complications reported in 65 studies (14 RCTs, 27 non-randomized controlled studies, and 24 observational studies) with 6,537 patients (mean age range 3.2 weeks to 39 years) who were diagnosed with PWS and were treated with PDL. Four of the studies included participants less than one year of age while the other 61 studies included patients over one year old. The authors reported that the overall pooled frequency of purpura was 98.3% (reported in 12 studies), for edema 97.6% (10 studies), crusting 21.5% (21 studies), blistering 8.7% (27 studies), hyperpigmentation 12.8% (58 studies), hypopigmentation 0.9% (57 studies), and scarring 0.2% (65 studies), and that acute adverse reactions were found to be common while the long-term permanent complications had a lower frequency. In the subgroup analyses, the authors reported that studies involving patients with a dark skin type showed a higher complication rate for hyperpigmentation, hypopigmentation and scarring compared to studies involving patients with a light skin type and that an increased complication rate was also noted in studies with a mean age above one year, when PDL treatment was performed on the torso or limb, in studies with a mean number of treatments greater than three, and when the spot size was five millimeters. Limitations of this study include the wide variation in quality of the included studies, incomplete data for baseline treatment in some of the studies, the inability for a meta-regression analysis to be performed and that the potential factors affecting the probability of complications could not be determined. The authors concluded that effective protective measures after treatment were very important for preventing scar formation and that overall, PDL treatment of PWS showed a high level of safety with a low chance of causing long-term complications. The Faurschou (2009) study previously cited in this policy was included in this systematic review.

Lekwuttikarn et al. (2023) conducted a long-term, single-center, retrospective, double-blinded study to evaluate the efficacy and complications of long-term laser treatment in patients with PWS. The study included 129 patients (70.54% male, median age at start of treatment 16 years) who had received a total of 4,141 laser treatment sessions (median of 49 sessions, interquartile range, 27-66 sessions) with PDL having been used in 88.63% of the sessions, followed by 1,064 long-pulse Nd:YAG (4.01%) and the 532 long-pulse Nd:YAG (2.63%). The authors performed a 25-year double-blinded retrospective chart review of patients diagnosed with PWS who underwent laser treatment and had photographic records before and after treatment available for review. The scores for improvement and color were independently evaluated by two dermatologists and then the improvement scores were divided into two groups with patients achieving > 50% improvement in the group defined as having a good outcome, and patients achieving ≤ 50% improvement group having a poor outcome. The authors reported that 53% of the patients achieved statistically significant (50%) improvement after six treatment sessions; however, none of these patients achieved complete clearance. The authors reported that the factors associated with > 50% improvement were male sex, Fitzpatrick skin type 3, and a greater number of treatments while factors that were associated with ≤ 50% improvement were hypertrophic PWS, lesions on the upper eyelid and nasal tip, and a follow-up interval of > 180 days. The authors were not able to compare the efficacy of each laser type due to the nonuniformity of the treatments rendered. The study was limited by the retrospective, single-center design, the use of various forms of laser therapy, combined types of laser and the heterogeneity of the treatment protocols, and The authors concluded that vascular lasers were a promising treatment for PWS and that multiple treatment sessions were required to achieve excellent results.

Wang et al. (2023) conducted a systematic review and meta-analysis to assess the safety and efficacy of photodynamic therapy (PDT) for 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 (four weeks to two to three months), and the follow-up period (two months to five 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.

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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 2,123 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 intralesionally for medically refractory lesions. A variety of other lasers are used for intralesional treatment or resection, though no conclusions can be drawn regarding the superiority of any of these modalities over any other. According to the review, laser studies generally found PDL more effective than other types of laser, but effects remain unclear as studies are heterogeneous and the role of laser vis-a-vis beta-blockers is not clearly described in the literature (Chinnadurai et al., 2016a).

Chinnadurai et al. (2016b) systematically reviewed studies of laser treatment of IH. A total of 29 studies addressing lasers: four RCTs, eight 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. Carbon dioxide (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 1,529 hemangiomas were included in the meta-analysis. This meta-analysis demonstrated an overall resolution rate of 89.1% with 6.28% incidence of adverse 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

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concluded that their experience confirmed the satisfactory clinical efficacy and safety of the 595 nm tunable PDL in the treatment of childhood superficial hemangioma.

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

AAP clinical practice guidelines for the management of IH 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

Minneci et al. (2024) conducted an RCT to compare the effectiveness of laser epilation (LE) as an adjunct to standard care versus standard care alone in preventing recurrence of pilonidal disease (PD) in adolescents and young adults. The single-center study included 302 participants between the ages of 11 to 21 years [median age 17 years, 157 (56.1%) males] with a history of at least one episode of PD without active disease. Participants were randomly assigned to each intervention group with 151 in the LE group and 151 in the standard care group. A total of 280 patients were followed up (131 laser treatment, 149 standard care) by the end of the study. The standard care (control) group participants each had an initial in-person visit during which they received a standardized level of education and training about hair removal and were given supplies to perform hair removal for six months with recommendation to continue regular hair removal until the patient reached 30 years of age. The LE group also received standard care in addition to a laser treatment every four to six weeks for a total of five treatments with either a diode 810-nm (for Fitzpatrick skin types I-IV) or Nd:YAG 1064-nm (for Fitzpatrick skin types V-VI) laser device. One-year follow-up was available for 96 patients (63.6%) of the group who received LE and for 134 (88.7%) of the group who received standard care. The authors reported that the proportion of patients who had a recurrence within one year was significantly lower in the LE treatment arm (23.2%) than it was in the standard care arm (33.2%) and that the LE group had significantly higher Child Attitude Toward Illness Scores (CATIS) at six months (3.8) than in the standard care group (3.6). The authors also reported that there were no differences between groups in either patient or caregiver disability days, or patient- or caregiver-reported health-related quality of life (HRQOL), health care satisfaction, or perceived stigma at any time point and that no differences were found between groups in disease-related health care utilization, disease-related procedures, or postoperative complications. Limitations of the study included the impact the COVID-19 pandemic had on the study (three month shut down of the clinic with no laser treatments being given, higher dropout rate for the LE group who could not access the treatments), the single center design, the lack of blinding for both the participants and the providers, and an incentive given to the control group only to complete the study to receive laser treatment after study completion. The authors concluded that LE as an adjunct to standard care significantly reduced one year recurrence rates of PD compared to standard care alone and that the results of this study provided further evidence that LE is safe and well tolerated in patients with PD.

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 PD. All of the 198 study participants underwent 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 PD. 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 PD 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.

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Check et al. (2022) conducted a prospective case series of 78 patients with mild 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 LE 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 six to eight weeks until all pit wounds were healed, and crease follicles were ablated with a minimum follow-up period of one year. The authors reported that 77 of the 78 patients had resolution of their PD after a mean of 3 ±2.5 LEs 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 nine patients who underwent LE alone and one 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 LE resulted in minimal morbidity and no activity restrictions.

In a systematic review that assessed the efficacy and safety of chronic 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 PD to determine its effect on disease recurrence. Thirty-five published studies were included. Of these, 28 studies were retrospective and seven were prospective. There were five comparative studies: two retrospective, one prospective observational, and two 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 PD recurrence rate after LHD ranged from 0% to 28% at a mean follow-up ranging from six months to five 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 PD. However, the literature published to date is heterogeneous and has limited generalizability. Additional research is needed to determine the effectiveness of LHD to prevent PD 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 PD. 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 LHR, 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 PD. 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 PD. 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 less than four 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 five LHD sessions and one patient completed four sessions. 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 three treatments. All 13 patients were

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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 PD and may be effective at decreasing PD recurrence. A prospective RCT is planned to determine effectiveness of LHD compared with chemical/mechanical depilation methods in preventing PD recurrence.

In a prospective RCT, Demircan et al. (2015) investigated the effects of LHD on patient satisfaction and recurrence in 60 patients who underwent PD surgery. Patients were divided in two groups of 30 patients each. Only the Karydakis flap reconstruction technique was performed in the first group. Two sessions of LHD were applied in the second group in addition to Karydakis flap reconstruction. The patients in the second group underwent LHD two weeks before and three weeks after the surgery for a total of two 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 two groups in the first week post operation considering the visual analogue scale (VAS) pain score and VAS satisfaction score. While there were statistically significant differences between the two groups in the first month post operation considering the VAS pain score, there were no statistically significant differences between the groups in terms of VAS satisfaction score in the first and third month postoperatively. In telephone interviews done one 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 PD 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 LHR following the excision of PD with conventional methods for hair removal. Patients undergoing surgery for PD were randomized to 2:1 with 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 six months (group II, n = 41). Group I patients received regular, monthly laser hair treatment sessions using Alexandrite laser for four sessions. Group I patients found the procedure comfortable with no complications. Group II patients reported difficulty in maintaining hair removal with conventional methods, and mostly, by the end of the first year, all cases stopped maintaining regular hair removal. There was no significant difference between the groups in the recurrence rate (0% for laser versus 4.4% for standard hair removal methods). Recurrence occurred in Group II patients (two cases) mostly due to failure in maintaining hair removal and area hygiene. The authors advocate the use of LHR after surgery for PD 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 PD 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 five to nine years. Fifty percent of the recurrent cases had drainage and healing by secondary intention before LHR. The investigators concluded that LHR after surgical interventions in PD 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 PD 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 three to eight 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 PD. 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 PD state that elimination of hair from the gluteal cleft and surrounding skin, by shaving or LE, may be used for both acute and chronic PD in the absence of abscess as a primary or adjunct treatment measure. The guideline advises that treatment usually includes one to four treatments of hair removal, cyst curettage, and phenol application into the cyst and tracts for complete resolution of the condition. A weak recommendation was made by ASCRS for LHR for treating PD 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).

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Italian Society of Colorectal Surgery (SICCR)

A consensus statement of the Italian Society of colorectal surgery (SICCR) for the treatment and management of PD 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

Chen et al. (2024) conducted a meta-analysis of 10 studies with a total of 413 children (59% male) to evaluate and explore the efficacy of CO_2 fractional laser in treating post-burn hypertrophic scars in children. The studies included seven retrospective studies (n = 323 patients), two RCTs (n = 53 patients), and one prospective cohort study (n = 49 patients). The authors reported that the meta-analysis showed that the average Vancouver Scar Scale (VSS) after surgery was significantly lower than before surgery and that, after CO_2 fractional laser, pigmentation, pliability, vascularity and height were improved compared to before treatment. The authors also reported that the average Visual Analogue Scale (VAS) after surgery was significantly lower than before surgery and that both Patient and Observer Scar Assessment Scale (POSAS)-Observer and POSAS-Patient were significantly lower than before surgery. The authors concluded that CO_2 fractional laser is beneficial to the recovery of hypertrophic scar after burn in children and can effectively improve the scar symptoms and signs in children. This meta-analysis included the Patel 2019 study summarized below.

Ma et al. (2024) conducted a systematic review and meta-analysis to investigate the effects of factors such as scar age, type of laser and laser treatment interval on burn scar outcomes in children. Seven studies (two RCTs, three prospective studies and two retrospective studies) were included in the meta-analysis with a total of 467 children (average age 10 years, male: female ratio of 1:1). Ablative CO_2 lasers were used in three studies (n = 254 patients), PDL was used in one study (n = 13 patients), non-ablative laser (Nd:YAG laser 1,064 nm) in one study (n = 50 patients) and a combination of PDL and ablative in two studies (n = 150 patients). The authors reported that laser therapy significantly improved VSS/POSAS, vascularity, pliability, pigmentation and scar height of burn scars and that subgroup analyses were performed due to the significant heterogeneity found between the studies. The subgroup analysis was reported by the authors to show that early laser therapy (provided less than 12 months from date of injury) significantly improved VSS/POSAS scores and vascularity compared to latent therapy (provided more than 12 months from date of injury). The authors also reported that non-ablative laser was most effective, significantly reducing VSS/POSAS, vascularity, pliability and scar height outcomes when compared to ablative, PDL and a combination of ablative and PDL treatments, and that shorter treatment intervals of less than four weeks significantly reduced VSS/POSAS and scar height outcomes compared to longer intervals of four to six weeks. Limitations of this meta-analysis include the significant heterogeneity among the included studies, the treatment protocols, and the populations in each study, as well as the lack of a control population. The authors concluded that the efficacy of laser therapy in the pediatric population was influenced by scar age, type of laser and interval between laser therapy application; however, significant heterogeneity in the studies suggested the need to explore other confounding factors that influence burn scar outcomes after laser therapy. The Patel 2019 study below was included in this meta-analysis.

In a similar systematic review and meta-analysis that focused on adults, Ma et al. (2023) evaluated whether factors such as time to initiation of laser therapy following scar formation, type of laser used, laser treatment interval, and presence of complications influenced burn scar outcomes in an adult population. The meta-analysis included 11 studies (five RCTs and six prospective studies) with a total of 491 adult patients (average age 33.6 years, ratio of 1:2 men to women) with any post-burn hypertrophic scars who underwent laser treatment (ablative CO_2 lasers on 337 patients, six studies; PDL on 57 patients, two studies; and non-ablative fractional lasers on 57 patients, three studies) for their scars. The authors reported that laser therapy significantly improved overall VSS/POSAS scores, vascularity, pliability, pigmentation and scar heigh of burn scars and that vascularity and scar height improvement were greater when laser therapy was performed more than 12 months post injury compared to when it was administered less than 12 months from date of injury. The authors also reported that PDL gave a greater reduction in VSS/POSAS scores compared to non-ablative and ablative lasers. The authors concluded that the efficacy of laser therapy was influenced by the time lapse after injury, the type of laser used and the interval between laser treatments; however, significant heterogeneity was observed among the studies reviewed suggesting the need to explore other factors that may affect scar outcomes. This study was limited by the heterogeneity of the study designs (e.g., types of lasers used, number of participants, treatment protocols) and possible confounding factors (e.g., age, sex of participants, location of burn, skin type, comorbidities), and the small number of studies available in the subgroup analyses.

In their Heath Technology Assessment on the use of fractional laser treatment (FLT) to address functional impairment in patients with a history of burn and traumatic scars, Hayes (2023) reviewed four published studies (including one

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prospective pretest-posttest study, one RCT, and two retrospective pretest-posttest studies) that included the use of carbon dioxide (CO_2) laser to deliver FLT. The overall quality of evidence for FLT for functional impairment secondary to burn or traumatic scars was rated as low while the quality of the evidence for FLT for functional impairment secondary to keloid scars due to burns or trauma, or for the use of lasers other than CO_2 lasers is rated very low due to lack of available studies. The report concluded that the overall low-quality body of evidence suggested that ablative FLT with CO_2 appeared to be reasonably safe and may result in statistically significant improvements in function in patients with functional impairments caused by hypertrophic scarring from burns and/or trauma; however, it was unclear whether FLT consistently led to clinically important improvements or whether it provided benefits beyond conventional scar care.

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 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 corticosteroid triamcinolone acetonide (TAC) impacts on keloid scar severity compared with cryosurgery plus 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 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 POSAS and 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 2,433 laser treatments. The majority of the studies utilized the VSS as a primary outcome measure. The 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

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range of 1-3 months between treatments. Indications for treatment included large, symptomatic hypertrophic scars with minimum treated areas ranging from 20 cm^2 to 100 cm^2. Response to therapy was measured in most of the studies with the 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 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-CO2 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 time between initial assessment and the median follow up was approximately five 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.

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 five 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 erbium-yttrium aluminum garnet (Er:YAG) 2,940 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 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 one to four sessions of treatment of burn scars with fractional CO_2 laser is associated with significantly improved outcomes.

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Patel et. al [2019, included in the Chen (2024), Ma (2024), Buhalog (2021) and Chloi (2021) systematic reviews above] 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 two-year period. Forty-nine 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.

Ashmawy et al. (2024) conducted a single center, prospective, right-left comparative study with 40 patients (ages 17 to 22 years, 45% males) with different clinical severities of acne vulgaris to compare the efficacy of low-level laser therapy in the treatment of inflammatory acne versus topical erythromycin 2% cream. All patients were evaluated using the GEA (Global Acne Severity) Scale, the Indian Acne Association (IAA) grading scale, with photographs before each session and at each follow up, and for patient satisfaction. Participants were instructed not to use any other treatment for acne during laser therapy and for three months after the last session. Each participant underwent split-face treatment: one side with eight treatments (twice per week for four weeks) of a low-level continuous infrared diode laser and the other side with topical erythromycin 2% twice daily. Participants were evaluated at the start of each session, two weeks after the end of the sessions and three months after the end of treatment. Three blinded dermatologists recorded percentage of improvement for each patient after completion of the treatment by comparing digital photographs before starting treatment and two weeks after the last session. The authors reported that there was no statistically significant difference between both sides as improvement of acne lesions was noted on both sides, although the sides treated with laser showed better results than the antibiotic side. The authors also reported that the laser side showed less relapse than the antibiotic side and patients were more satisfied with laser treatment due to minimal side effects and less relapse. The authors concluded that low level continuous infrared diode laser rendered in eight treatment sessions represented a cheap, safe, and effective non-invasive therapeutic option for acne vulgaris. Limitations of the study include the single center design, the small, homogenous study population, and the short follow-up period.

In their prospective, single center, comparative study that assessed the efficacy of fractional CO_2 laser versus Nd:YAG laser for acne vulgaris therapy, Hammoda et al. (2023) enrolled 30 adult women between 18 to 24 years of age who were experiencing mild to severe acne according to the GEA scale. Each participant underwent both types of laser treatments

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in a randomized, split-face design at a 14-day intervals for four sessions. Primary assessment was done by counting the number of acne lesions at one month after the last session while the secondary assessment included severity grading by the GEA scale, acne lesions improvement percentage, and patient satisfaction. The authors reported that, after treatment (four weeks after the final session), a statistically significant reduction in mean inflammatory count in the fractional CO_2 side compared to the Nd:YAG side was detected, but no statistically significant difference was found in mean noninflammatory acne count between both therapeutic modalities; however, after three months' follow-up, the fractional CO_2 showed a statistically significant reduction in mean inflammatory and noninflammatory lesions compared with Nd:YAG. The study is limited by the small sample size, the single center design, the short follow-up period and the homogeneity of the study population. The authors concluded that fractional CO2 and Nd:YAG lasers were both safe, tolerable, and highly effective therapeutic options for acne, although fractional CO_2 laser had a higher percent of improvement and patient satisfaction compared with long pulsed Nd:YAG.

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 3,520 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 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.

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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. (2020) 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 one to three months, and the follow-up period was between three weeks and three 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 1,064 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 micro needling 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 870-1,200 nm) and the diode laser (1,450 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, four case reports, and two retrospective studies met the inclusion criteria. Seven of the studies were high quality. The most common photosensitizers used were 5-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 (4,211 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)

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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 eight weeks after final treatment. Only a few studies assessed outcomes at more than three months after final treatment. The authors concluded that high-quality evidence on the use of light therapies for individuals with acne is lacking. There is low certainty of the usefulness of MAL-PDT (red light) or ALA-PDT (blue light) as standard therapies for people with moderate to severe acne. According to the authors, carefully planned studies, using standardized outcome measures, comparing the effectiveness of common acne treatments with light therapies are needed.

Keyal et al. (2016) evaluated the evidence regarding safety and efficacy of 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, three were clinical trials with control, 14 were clinical trials without control, six were RCTs and one 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 a 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 enrollment. Of these, 98 (94%) were randomized and 90 (92%) underwent at least one treatment session. Five patients decided to withdraw their consent before receiving a first treatment, and three patients were not treated as the study enrollment period was ended. Efficacy was assessed through changes in acne severity using the Investigator's Global Assessment (IGA) scale and inflammatory acne lesion counts, both evaluated against baseline at weeks six 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 three (moderate) demonstrated a success rate (two or greater grade drop) of 45.3% whereas patients with a baseline IGA grade of four (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 three 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 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

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authors, more RCTs are needed to determine the types and concentrations of photosensitizers and light sources, and the duration of light activation and incubation.

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 to 27 years, with mild-to-severe acne and Fitzpatrick skin phototype IV were enrolled in the study. The patients were equally divided into two groups. The first group was treated by BP while the second group was treated by IPL. Treatment with both BP and IPL resulted in considerable improvement of the acne after five 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 two and four 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.

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 the 2024 updated guideline of care for the management of AV, the AAD stated that the available evidence remains insufficient to develop a recommendation on the use of laser and light-based devices (including 585-595 nm pulsed dye laser, neodymium-doped yttrium aluminum garnet laser, 1,450 diode laser, potassium titanyl phosphate laser, infrared light-emitting diode, 635-670 nm red light, combined 420 nm blue light and 660 nm red light, 589 nm/1,319 nm laser, or intense pulsed light), microneedle radiofrequency device, or photodynamic therapy with aminolevulinic acid for the treatment of acne. According to the AAD, RCTs with long-term follow-up and comparative effectiveness research are necessary to examine and compare patient-centered acne treatment outcomes. 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 (Reynolds et al. 2024).

Onychomycosis

The quantity and quality of the evidence is insufficient to recommend light and laser treatment for the treatment of onychomycosis (OM). Published studies have mixed results and the optimal treatment regimen remains unclear as does the long term efficacy, None of the peer reviewed, published studies addressed the efficacy of laser therapy on medical complications (e.g., cellulitis, sepsis, osteomyelitis) of OM. Additional research is needed to determine efficacy and safety and to clarify patient selection and treatment parameters.

Ramzy et al. (2024) conducted a prospective, one-arm, single-center study to assess the use of 1,064-nm neodymium-doped:yttrium aluminum garnet (Nd:YAG 1064) on 213 mycotic nails (204 toenails in 30 patients and nine fingernails in three patients) in 31 adults (16 males, mean age 53.5 ±13.1 years) to assess the safety and efficacy of laser treatment for OM. Study participants presented with mostly severe *T. rubrum*-positive (87.1%) infections and most (61%) had a family history of OM. Comorbidities included hypertension (38.7% of participants), hyperlipidemia (35.5%) and/or diabetes (12.9%). While this was the first treatment for OM for 16 study participants, the remaining participants had previously been treated with topical medication (n = 9), laser therapy (n = 6), terbinafine (n = 6), itraconazole (n = 1) and/or fluconazole (n = 1). Each participant was evaluated for pain and discomfort at each treatment session using the 10-point visual analogue scale (VAS), and the mycological and clinical cure rates were determined three months following the last treatment session with an online Scoring Clinical Index for Onychomycosis (SCIO) calculator. OM was mostly calculated to be severe, with a mean SCIO score of 21.9 ±8.9 at baseline. All patients completed the full course of treatment which

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consisted of eight Nd:YAG 1,064 nm laser treatment sessions to each affected nail once a week for four consecutive weeks and then once every two weeks for an additional eight consecutive weeks. The authors reported that the treatment was well-tolerated (mean pain scores ≤ 1.3 at each session) with no reports of nail deformity or burns and that mycological cure was achieved in four (12.9%) participants with visual improvements noted in 10 (32.3%) of the participants. Limitations of the study include the one-arm, single center design, the small population size, the unreliability of determining mycological cure rates with superficial nail layers, the short-term follow-up period, and the heterogeneity of the comorbidities and previous treatments of the study population. The authors concluded that Nd:YAG 1,064 nm laser was safe and partially effective for the management of mild-to-moderate OM in diverse populations but was largely ineffective in addressing severe cases. The authors recommended further study for specific subsets of patients to determine treatment parameters and for studies comparing the mycological and clinical efficacy of laser therapies alone and in combination with topical therapies.

Zhang et al. (2022) conducted a systematic review and meta-analysis of 12 RCTs with 869 patients (431 in the experimental group and 438 in the control group) to evaluate the efficacy and safety of laser and topical antifungal agent combination therapy for OM. The studies included six that applied CO_2, five employed Nd:YAG, and one study used Er:YAG laser. The level of evidence of complete cure rate and clinical effective rate were low-quality evidence, while the evidence of mycological cure rate and satisfaction of participants' rate were moderate-quality evidence. The authors reported that laser and topical antifungal agent combination therapy was superior to topical antifungal agents alone in terms of complete cure rate, mycological cure rate, clinical effective rate, and patient satisfaction. Their subgroup analysis of outcome indicators (mycological cure rate and clinical effective rate) demonstrated that both CO_2 laser therapy combined with topical antifungal therapy and 1,064-nm Nd:YAG laser therapy combined with topical antifungal therapy showed better results than topical antifungal therapy alone. The authors reported no adverse events were identified except for three studies that reported transient burning sensation without treatment and mild to moderate pain, which were well tolerated. The authors concluded that their study showed that laser and topical antifungal agent combination therapy is effective for OM, although they recommended more large-scale and well-designed RCTS are warranted. Limitations of the study include the heterogeneity of the study designs, the types of OM, the severity of the disease, the duration of treatment, type, fluency and pulse of the laser treatment, and the follow-up period in the included studies which limited the number of studies available for meta-analysis for each type of laser. The authors recommended more clinical trials be conducted for a more comprehensive analysis.

In a single-center, randomized parallel study by Kandpal et al. (2021) sought to compare the efficacy of Q-switched Nd:YAG laser as a monotherapy in comparison to itraconazole. Patients with confirmed cases of OM (finger or toenail) who had not received treatment six months before presentation were randomly allocated to two groups of 50 adults (age range 20 to 45 years) each with the participants being well matched with no significant statistical difference in age and gender between the two groups. Dermatophyte infection accounted for 66% of the participants in the laser group and 72% of the participants in the itraconazole group. Onychomycosis severity index (OSI) and visual analog scale (VAS) score were used to assess nail involvement at the start of the study, at three months and at one year after enrollment. In the Nd:YAG group (70% male), patients with OM were treated with 12 weekly sessions of laser therapy while the itraconazole group (74% male) received 200 mg twice daily for one week per month for three months. The authors reported that the VAS and OSI showed statistically significant improvements at three and 12 months in the Nd:YAG group, although OSI was comparable in both groups at 12 months. The authors also reported that both dermatophytes as well as non-dermatophytes responded well to laser treatment, although non-dermatophytes responded better to laser. Limitations of the study include the single-center design, the lack of measurement of the nail growth rate, the use of a negative culture as a measure of the cure rate, and the small sample sizes. The authors concluded that Q-switched Nd:YAG laser was effective in inducing nail clearance in OM and was better than itraconazole in managing non-dermatophyte OM.

Han et al. (2021) conducted a meta-analysis of five RCTs with 497 patients with OM to compare the efficacy and satisfaction rates of CO_2 laser therapy with topical agents. In 253 patients, CO_2 laser treatments were combined with topical agents (tioconazole, luliconazole, tazarotene, clotrimazole, and lidocaine), while 161 patients received independent topical antifungal therapy and 50 patients received CO_2 alone. The duration of treatment varied from three to six months. All five studies were assessed as medium quality or above. The authors reported that the meta-analysis showed that combined CO_2 laser and topical treatments significantly increased efficacy 5.38-fold when compared with topical agents alone, with low heterogeneity observed among studies. The author also reported that mycological clearance comparison rates were also improved by combined treatments (60%) when compared to topical agents (48%) and that patient satisfaction outcomes showed significant differences between the combined treatment group versus the group that received topical agent alone; however, no statistical significance was observed between the combined group versus the CO_2 laser treatment alone group. Finally, the authors reported that subgroup difference analyses showed no statistical significances ($p = 0.46$), which indicated similar effects for both types of CO_2 therapy used in the studies (ablative CO_2 and fractional CO_2) for OM. The meta-analysis was limited by an unclear risk of allocation concealment in all but one study, the limited number of published RCTs available for inclusion, the heterogeneity of topical agents utilized, types of

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CO_2 used and treatment courses among studies, and the small sample sizes in each of the three study groups. The authors concluded that combined therapy may exert positive effects and satisfactory safety for patients with moderate to severe OM; however, the authors recommended more comprehensive RCTs to determine optimal combination options and appropriate dosages.

In a Cochrane Database of Systematic Reviews, Foley et al. (2020) sought to assess the clinical and mycological effects of tropical drugs and device-based therapies on OM. While the review itself included 56 studies (12.501 participants), the review included only three studies (112 participants) that compared 1,064-nm Nd:YAG laser to no treatment or sham treatment. The authors stated that they were uncertain if there is a difference in adverse events and that there may be little or no difference in mycological cure at 52 weeks (very low-quality evidence; two studies with 85 participants) and that complete cure was not measured. The authors stated that there was not enough evidence to recommend or discourage the use of 1,064-nm Nd:YAG laser, or photodynamic therapy and that the small number of device-based studies did not allow them to meet their objective of drawing conclusions on the clinical and mycological effectiveness of device-based interventions.

In their systematic review and meta-analysis on the curative effects and safety of laser treatment for OM, Ma et al., (2019) evaluated 35 published trials (five RCTs, 14 comparison studies and 16 self-control studies) that included a total of 1,723 patients and 4,278 infected nails. The authors stated that the included studies did not show evidence of publication bias and the risk of selective reporting was determined as being low, and that the majority of the studies were scored as being of medium quality or above. The authors reported that the overall mycological cure rate was 63% with subtype analysis showing the mycological cure rate of long pulse width 1,064-nm Nd:YAG laser treatment was 71.0%, the mycological cure rate of CO_2 fractional laser treatment was 45.0% and the mycological cure rate of perforated CO_2 laser treatment was 95.0%. According to the authors, this demonstrated that the overall efficacy of laser treatment was moderately lower than that of conventional oral medications, but that laser treatments also produced less reported side effects, such as damage to the liver and kidney or gastrointestinal reactions. The authors also reported that there were reports of hemorrhage after treatment in one study, larger wound on the nail deck and nail bed and formation of brown eschar with CO_2 laser treatment, and that the majority of patients reported experiencing a tolerable mild to moderate burning sensation during laser treatment. Limitations of the study included the heterogeneity of the studies that were included with different ages, duration of disease, and duration of follow-up. The authors concluded that laser treatment of OM was effective and safe; however, they recommended more RCTs are necessary to verify their findings.

Yeung et al. (2019) conducted a systematic review and one-arm meta-analysis of 22 prospective trials (four RCTs and 18 uncontrolled trials) with a total of 755 participants to examine the evidence on efficacy of laser treatment of OM. All trials except two applied 1,064 nm Nd:YAG lasers to treat OM. The authors analyzed the studies with participants as the unit of analysis (UOA; n = 13) separately from the studies with nails as the UOA (n = 7), and there were two studies that used both participants and nails as the UOA. The authors reported that, when results were reported based on participants as the UOA, mycological cure (n = 12 trials) was achieved in 70.4% of participants, clinical improvement (n = 5 trials) in 67.2%, and complete cure (n = 3 trials) was achieved in 7.2% of participants although high statistical heterogeneity was detected in all three analyses. When the authors evaluated trials using nails as the UOA, they reported mycological cure (n = 3 trials) was 22.9%, clinical improvement (n = 7 trials) was achieved in 56.2%, and complete cure (n = 2 trials) was achieved in 24.5%, all with significant high heterogeneity detected. The authors concluded that the current level of evidence was limited, and, with high heterogeneity, it was difficult to assess the true efficacy of laser treatment for OM. The authors recommended larger RCTs with well-defined methodology be conducted. Limitations included the heterogeneity of the study designs and treatment parameters, the short follow-up period (1-12 months), the variability in definitions of outcome, choice of analysis, and diagnostic techniques, lack of information in 17 trials for the clinical severity and duration of OM, and the small number of RCTs available for inclusion.

Rosacea and Rhinophyma

The quantity and quality of the evidence is insufficient to recommend light and laser therapy for the treatment of rosacea and rhinophyma. The studies are limited by small sample sizes, uncontrolled design, heterogeneous laser types and treatment protocols, as well as short follow-up periods and they are insufficient to determine significant positive clinical outcomes. Additional research is needed to determine efficacy and safety and to clarify patient selection and treatment parameters.

Piccolo et al. (2024) conducted a single-center, prospective study to test the efficacy of intensity pulsed light (IPL) therapy for the treatment of vascular lesions. The study included 39 adults (15 males, age range 18 to 75 years) affected by telangiectasia (11 patients) , rosacea (17 patients), erythrosis (nine patients), and poikiloderma (two patients). Each participant received IPL therapy in three treatment sessions spaced one month apart with follow-up performed at 21 days and 90 days following the last IPL session. Three-dimensional and dermoscopic clinical photographs were captured and evaluated using a five-point scale before each treatment, immediately after, and three days, 21 days, 45 days, and three

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months after the last treatment session. The authors reported that 21 patients (53.8%) achieved excellent improvement, 13 patients (33.3%) achieved good improvement, three patients (7.7%) achieved moderate improvement, and two patients (5.1%) achieved mild improvement. The study was limited by the single-center design, the small sample size, and the short follow-up period. The authors concluded that the IPL system may represent successful treatment to improve vascular lesions that are resistant to laser therapy.

In their prospective, controlled, single-center study comparing the efficacy and safety of the variable-sequenced, large-spot 532 nm KTP laser to the 595 nm PDL in treating rosacea, Nguyen et al. (2024) enrolled 45 adults (mean age 51 ±11.6 years, 78.6% female) with rosacea who were assigned in a 2:1 allocation to undergo either KTP laser (n = 30 patients) or PDL therapy (n = 15 patients). Each patient received up to three treatment sessions at intervals of 6-8 weeks with a follow-up visit scheduled at six weeks post-treatment. The primary end point was the improvement of rosacea-associated erythema at six weeks after last treatment session compared with baseline. Three-dimensional photos were obtained at the beginning of each treatment session and at the six week post-treatment visit. The photos were assessed by two blinded independent board-certified dermatologists for improvements using the Global Aesthetic Improvement Scale. The authors reported that patients who received KTP treatment reported a significant improvement in flushing and persistent erythema, while those In the PDL group also noted a reduction of persistent erythema but no significant difference in flushing. The authors also reported that the patients who received KTP rated their pain intensity significantly lower than those in the PDL group, and that all patients in the KTP group experienced post-treatment mild-to-moderate swelling and erythema with approximately 20% who also exhibited purpuric reactions that lasted for 1.3 ±2.7 days. In the PDL group, the authors reported that all patients reported swelling and purpura after treatment, which lasted for an average of 6.9 ±3.9 days and that around 35% developed crusts, which lasted for 2.2 ±3.5 days. No reports of serious adverse effects were reported by the authors, and no patients in either treatment group discontinued the study due to adverse events. The study was limited by the single-center design, small study population, short follow-up period, lack of control of external factors such as lifestyle, diet and UV exposure, and the use of three different PDL systems. The authors concluded that both KTP laser and the PDL are similarly effective in treating rosacea-associated persistent erythema and telangiectasia and that KTP appeared to have a positive impact on flushing, which could not be proven with the PDL. However, secondary symptoms of rosacea, such as burning sensation, edema, and dry sensitivity, seemed to respond more favorable to PDL treatments, although the KTP exhibited fewer post-treatment reactions.

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 four monthly treatments with follow-up sessions at one month (visit 5, short-term) and three months (visit six, 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 (fifth visit) evaluation and that three months after the fourth treatment (on their sixth 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 sixth 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 2,940 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 six-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 four-week intervals and were followed up at four weeks after the last treatment session. Skin type, sex, age, lesion site, severity of erythema and telangiectasia, VISIA 6.0 Complexion

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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 six 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 two 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 one 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 ≤ six 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 a split-face, double-blind RCT, Alam et al. (2013) compared the effectiveness of microsecond 1,064 nm Nd:YAG laser with non-purpuragenic 595 nm PDL for diffuse facial erythema or erythematotelangiectatic rosacea (ETR). Bilateral cheeks received four 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

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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-purpuragenic 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 two 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 six 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 CO_2 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.

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 CO_2 laser and Er: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)

In the NRS's Practical Guidance that addresses rosacea, the NRS identified monotherapies and multimodal treatment approaches for the clinical management of rosacea including topical, systemic, laser and light, alternative, and combination therapies. The NRS stated that there is currently no single treatment that is fully curative for rosacea and that the quality of evidence for available treatments varies depending on the modality with topical therapies having the highest level of evidence. Regarding the use of light and laser therapies, the NRS guidance states the following:

- Phenotype-based strategies: Lasers and intense pulsed light (IPL) can be considered as an alternative treatment that can be used, although the available evidence mainly comprises small and/or uncontrolled studies.
- Papules and pustules: Lasers, IPL, and PDL can be used, although the evidence remains insufficient.
- Phymatous features: Chronic and severe phymatous disease may require surgical intervention, such as ablative lasers, electrosurgery, electrocautery and dermabrasion, to remove excess tissue and recontour deformations.

The most frequently used types of light and laser therapies include PDL, IPL, potassium titanyl phosphate (KTP) laser, Nd:YAG, CO_2, and Er:YAG lasers. The Practice Guidance further states that light therapies and lasers have been

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successful in the management of rosacea features, particularly telangiectasias and phymatous change although the quality of evidence is narrow (Nguyen et al. 2024).

The NRS has also 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).

Vitiligo

The majority of published peer-reviewed studies address the efficacy and safety of excimer laser (EL) on re-pigmenting vitiligo lesions rather than the efficacy of EL to affect the autoimmune destruction of melanocytes/disease process itself. Currently, the quantity and quality of evidence addressing the ability of EL to affect the clinical disease process of vitiligo or to prevent sequela related to vitiligo is insufficient to recommend its use. Future studies are needed to determine the efficacy and safety of excimer laser to impact vitiligo's disease trajectory.

Li et al. (2024) conducted a systematic review and network meta-analysis to compare the efficacy and safety of excimer laser (EL)-based combination regimens in improving pigmentation. The authors stated that while vitiligo may not endanger a patient's life, it may be stigmatizing and lead to psychological disturbance, increasing the risk of psychiatric disorders and stress, and seriously affect the quality of life for patients with vitiligo. The meta-analysis included 11 RCTs with 348 patients (38.2% male, aged four to 91 years old) that included nine different interventions. The authors reported that EL combined with antioxidants (98.8%), with calcipotriol (59.8%), and with tacalcitol (59.6%) were the optimal interventions for achieving re-pigmentation rates greater than 75% while EL alone (77.6%), with tacalcitol (61.7%), and combined with antioxidants (57.2%) were the three interventions with the highest rate of treatment failure. Limitations of the study include the fact that all 11 of the RCTs were single-center studies, many had small sample sizes, data limitations, and short follow-up periods The authors concluded that EL combined with antioxidants was the preferred regimen for treatment of vitiligo while EL alone was the regimen with the highest rate of treatment failure. The authors recommended larger, high-quality, multicenter RCTS to validate or update their findings.

In their Evidence Analysis Research Brief, Hayes (2023) reviewed the abstracts of four published peer-reviewed studies (two RCTs and two systematic reviews with meta-analyses) related to the efficacy of excimer laser therapy (ELT) on re-pigmentation of vitiligous lesions and determined that an adequate amount of evidence is available for review. Since this report was only a review of abstracts, Hayes stated that it was not intended to draw conclusions about safety and effectiveness as that would require a full-text review of the evidence.

In their prospective, single-center RCT to assess the efficacy and safety of combining the 308-nm excimer lamp (EL) with Tacrolimus 0.1% ointment, compared to Tacrolimus 0.1% ointment alone, for treating pediatric vitiligo, Alshiyab et al. (2023) recruited 50 pediatric patients (ages five years to 17 years) with non-segmental vitiligo affecting less than 10% body surface area and randomly assigned them to either receive Tacrolimus 0.1% ointment twice daily along with EL (Group A; n = 25 patients, median age 12 years, 56% female) or Tacrolimus 0.1% ointment alone, administered twice daily (Group B; n = 25 patients, median age 14 years, 60% female). All participants underwent a six-week wash-out period before enrollment. Re-pigmentation percentages were evaluated after 30, 90, and 180 days. The authors reported that the efficacy (measured by re-pigmentation percentage) did not differ significantly between groups at one month, but that Group A showed a higher efficacy in subsequent follow-ups with a median re-pigmentation percentage of 40% at three months and 65% at six months while the patients in Group B reported a median re-pigmentation of 15% at three months and 30% at six months. The authors also reported that none of the patients in Group B experienced any adverse reactions while 16% of the patients in Group A experienced mild erythema. Limitations of the study include the small sample size, the short follow-up period, the single-center design, and the lack of diverse ethnicities, skin types and genetics. The authors concluded that the combination of Tacrolimus with EL yielded superior re-pigmentation results compared to the use of Tacrolimus alone in pediatric patients with vitiligo.

Tabassum et al. (2021) conducted a single-center, retrospective case series on patients with vitiligo who had either received EL (Group A; mean age 19.4 years, 32.5% male) or targeted UVB (TUVB; Group B; mean age 23.4 years, 35% male) to compare the safety and efficacy of these two treatment options for re-pigmenting vitiligo lesions. Data was retrieved from the medical records of 40 age and sex matched (with almost similar sites of involvement) patients who were included in each group. A total of 69 lesions were treated in Group A and 97 lesions in Group B. Patients who had been on any concomitant therapy when they were receiving phototherapy, who had been on any immunosuppressive drugs or immunomodulator drugs for vitiligo, and patients with acrofacial vitiligo were excluded from the study. Each of the 80 patients had received phototherapy sessions twice weekly for a minimum of 30 sessions or until 90% to 100% re-pigmentation. The authors reported that an excellent response (75%-100% re-pigmentation) was achieved in 68.1% of lesions in Group A and 46.4% of lesions in Group B, and that 82.6% of Group A participants and 76.3% of Group B

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participants responded with at least 50% re-pigmentation. The authors also reported that patients in Group A needed fewer doses (13.75 versus 19.37) and less cumulative dose (6.14 versus 7.69 J/cm^2) to achieve complete or near complete re-pigmentation. Finally, the site of the treated lesion appeared to affect the response to treatment with the best response occurring on face and neck followed by lower limb in Group A and the face and neck area followed by the trunk in Group B. The authors concluded that the study demonstrated the excellent re-pigmenting efficacy of both EL and TUVB devices in vitiligo and that targeted phototherapy with EL demonstrated better re-pigmenting efficacy than TUVB in vitiligo on almost all areas of the body. Limitations of the study include the single center, retrospective design and the small population included.

In their multicenter, three-arm, parallel-group, pragmatic, placebo-controlled RCT the Home Interventions and Light therapy for the treatment of Vitiligo Trial (Hi-Light Vitiligo Trial) to evaluate the comparative safety and effectiveness of handheld narrowband UVB (NB-UVB) to topical corticosteroid (TCS) as a treatment for localized vitiligo, Thomas et al. (2021) enrolled a total of 517 participants (398 adults and 119 children aged > five years). Study participants all had nonsegmental vitiligo affecting approximately 10% or less of body surface area, with at least one vitiligo patch that had been active in the last 12 months. Each participant received an NB-UVB light unit (active or dummy) and either a TCS or a placebo. Participants were randomized 1:1:1 to one of the three arms with 173 participants in the TCS only group, 169 in the NB-UVB only group and 175 in the combination group. Primary outcome data were available for 370 (72%) participants. Participants were enrolled for up to 21 months (9 months of treatment, 12 months of follow-up) and were seen on two consecutive days at baseline for recruitment and training, and then at three, six, and nine months to assess outcomes. Follow-up thereafter was by three-monthly questionnaires. The authors reported that the proportions with target patch treatment success were 17% in the TCS only group, 22% in the NB-UVB group, and 27% in the combination group and that combination treatment was superior to TCS but that NB-UVB alone was not superior to TCS alone. The authors also reported that participants using interventions with ≥ 75% expected adherence were more likely to achieve treatment success, but the effects were lost once treatment was stopped. Adverse effects included localized grade 3 or 4 erythema reported in 62 (12%) of participants (including three participants in the dummy light group) and skin thinning was reported in 13 (2.5%) participants (including one with placebo ointment.) The authors concluded that combination treatment with home-based handheld NB-UVB plus TCS was likely superior to TCS alone for treatment of localized vitiligo and that the combination treatment protocol was relatively safe and well tolerated, although it was only successful in around one-quarter of the participants.

Poolsuwan et al. (2021) conducted a prospective, single-center, randomized, single-blind comparison study to compare efficacy between 308-nm excimer light and 311-nm narrowband ultraviolet B (NB-UVB) phototherapy in 36 adults (aged 18 to 65 years) with symmetrical vitiligo lesions. The study included 36 symmetrically paired vitiligo lesions on the same anatomical area. One side of the lesion was treated with localized 308-nm EL and the opposite side was treated with targeted 311-nm NB-UVB assigned randomly by a computer with the results of the randomization sequencing blinded to investigators. All lesions were treated with the same protocol three times per week for a total of 48 treatment sessions. Re-pigmentation was evaluated based on both clinical and photographic observations performed by three study-blinded independent dermatologists at the pretreatment session, and then every month until the end of study using the Vitiligo Area Scoring Index (VASI) and grading photographs of the lesion that had been taken at each session. The authors reported that a significantly lower VASI score and a higher grade of re-pigmentation were observed in 308-nm EL treated side when compared to the 311-nm NB-UVB side. The authors reported that nine lesions (25%) that were treated with the 308-nm EL versus five lesions (13.89%) treated with 311-nm NB-UVB achieved excellent re-pigmentation, and that the 308-nm EL and 311-nm NB-UVB–treated sides obtained 25% re-pigmentation within a mean of 19.42 sessions and 26.25 sessions, respectively, with no significant difference in mean cumulative UV dosage and with similar phototoxicity on both sides. The authors concluded that localized 308-nm EL appears to be more effective and more rapid in inducing re-pigmentation than targeted 311-nm NB-UVB for treatment of vitiligo. Limitations of the study include the single-center design, the small sample size and the short (three month) follow-up period.

Sun et al. (2015) conducted a systematic review of seven RCTs with 390 patients (ages two to 66 years) with vitiligo to evaluate the efficacy and safety of 308-nm excimer laser on vitiligo. Primary outcomes for the study were re-pigmentation rates of ≥ 50% (four studies), ≥ 75% (four studies) or 100% (two studies) and secondary outcomes were the cumulative UV dose (one study), the re-pigmentation scores (two studies) and side effects (six studies). Three studies compared the efficacy and/or safety of 308-nm excimer laser with 308-nm excimer lamp, while the other four studies compared 308-nm excimer laser with NB-UVB, The authors reported that no significant differences were seen between 308-nm excimer laser and 308-nm excimer lamp on either ≥ 75% or ≥ 50% re-pigmentation rate, or between 308-nm excimer laser and narrowband-ultraviolet B (NB-UVB) on either 100% or ≥ 75% re-pigmentation rate. The authors also reported that more vitiligo lesions achieved ≥ 50% re-pigmentation rate by 308-nm excimer laser treatment than by NB-UVB treatment. Limitations of the study include the lack of adequate randomization in five of the studies, incomplete outcome data in six of the seven studies, the heterogeneity of the study designs and treatment protocols, and the small sample sizes. The authors concluded that the 308-nm excimer laser showed equivalent efficacies to the 308-nm excimer lamp control and

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NB-UVB control concerning ≥ 75% re-pigmentation rate of vitiligo patches. The authors recommended future studies include high methodological quality, low risk of bias and larger sample size to confirm their conclusion.

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.

Excimer Laser

There are several excimer laser devices that have been approved by the FDA through the 510K premarket approval process for ultraviolet lamps for dermatologic disorders. Product specific information can be found through the following website with the use of product code FTC: https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 18, 2024)

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 13, 2024)

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 13, 2024)

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 13, 2024)

Laser Therapy

Several flashlamp-pumped pulsed dye lasers (FLDPLs), Xenon-chloride (XeCl) excimer lasers, neodymium-doped yttrium aluminum 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 13, 2024)

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Policy History/Revision Information

Date	Summary of Changes
10/01/2025	• Created state-specific policy version for the state of Nebraska (no change to coverage guidelines)
01/01/2025	**Related Policies** • Added reference link to the Medical Policy titled *Outpatient Surgical Procedures – Site of Service* **Coverage Rationale** • Replaced language indicating "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*" with "laser hair removal is proven and medically necessary for the treatment of pilonidal sinus disease that has been or is being treated with surgery *for control of hair regrowth*" • Revised list of conditions for which treatment with light and laser therapy is unproven and not medically necessary; added "onychomycosis" • Added language to indicate excimer laser therapy is considered cosmetic and not medically necessary for treatment of vitiligo **Applicable Codes** ***Excimer Laser Therapy*** • Added CPT code 96999 ***Laser Hair Removal*** • Added CPT code 17999 • Removed CPT code 17380 **Supporting Information** • Updated *Description of Services, Clinical Evidence, FDA*, and *References* sections to reflect the most current information • Archived previous policy version CS069.R

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