Light and Laser Therapy (for North Carolina Only)

Policy Number: CSNCT0337.04
Effective Date: January 1, 2025

➲ Instructions for Use

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Related Policy

- Cosmetic and Reconstructive Procedures (for North Carolina Only)

Application

This Medical Policy only applies to the State of North Carolina.

Coverage Rationale

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

- Port-wine stains
- Cutaneous hemangioma/hemangiomata

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 health service. Benefit coverage for health services is determined by federal, state, or contractual requirements and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

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

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

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CPT Code	Description
Cutaneous Vascular Lesion	
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
Therapy 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

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 (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

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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.

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 repigmentation 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,

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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 4141 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 1064 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 (4 weeks to 2-3 months), and the follow-up period (2 months to 5 years). In their evaluation of bias risk, the authors determined that 23 out of 26 non-randomized experiments were of poor quality and the three RCTs were of moderate quality. The authors reported that 51.5% of the patients achieved a 60% improvement after treatment with PDT and that 20.5% of patients achieved a ≥ 75% improvement (GRADE score: very low), The authors stated that PDT efficacy varied based on sex, age, the type, and location of the PWS, and the PDT treatment parameters. The authors concluded that PDT is a safe and effective treatment for PWS.

In a systematic review and network meta-analysis (NMA), Fei et al. (2020) reviewed the efficacy and adverse effects of different therapies to address infantile hemangioma (IH). They evaluated 30 randomized controlled trials (RCTs) with more than 20 different therapeutic regimens and a combined 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)

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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 CO2 and Nd:YAG lasers typically reported some resolution of lesion size, but heterogeneity among studies limited the ability to draw conclusions. The authors concluded that studies of laser treatment of IH primarily addressed different laser modalities compared with observation or other laser modalities. PDL was the most 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 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)

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

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

A prospective study by Piccolo et al. (2022) was performed to assess the efficacy, safety, and reproducibility of a novel intense pulsed light (IPL) protocol as a monotherapy in the treatment of acne of the chest and back. A total of 50 patients ranging from 18 to 40 years of age (mean age 23.8 years old) with Fitzpatrick Skin Types II to III and moderate

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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. 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 (2020) et al. assessed the safety and efficiency of intense pulse light (IPL) therapy in the treatment of acne vulgaris. The authors reviewed eight RCTs, including the El-Latif (2014), the Liu (2014a) and the Mohamed (2016) studies cited below. Three of the eight trials applied IPL in combination with other therapies, while others performed IPL alone. The course of treatment varied from 1 to 3 months, and the follow-up period was between 3 weeks and 3 months in those trials that reported the length of follow-up. The meta-analysis included a total of 450 participants and concluded that IPL is not as efficient as other supplementary therapies as the results of the IPL group's mean percentage reduction of inflammatory acne lesions (MPRI) was poorer than that of the control group that was treated with pulsed dye therapy and that the efficiency of IPL was poor among African and Asian populations. They also found that the difference in efficiency between IPL and 1064 nm Nd:YAG was not statistically significant. The authors noted that there are limitations to the meta-analysis, including the heterogeneities among the studies including the use of various filters for the IPL system, various pulse modes, number of treatment sessions and the interval period. Other limitations they identified include a lack of studies with large sample size, and that all the studies include in the meta-analysis were single center.

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

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

Boen et al. (2017) performed a systematic review of the literature for PDT used for acne and critically evaluated the studies. Sixty-nine clinical trials, 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.

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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) combined with PDL to C/BPO alone. None of these showed any clinically significant effects. Although the primary endpoint of the review was long-term outcomes, less than half of the studies performed assessments later than 8 weeks after final treatment. Only a few studies assessed outcomes at more than three months after final treatment. The authors concluded that high-quality evidence on the use of light therapies for individuals with acne is lacking. There is low certainty of the usefulness of MAL-PDT (red light) or ALA-PDT (blue light) as standard therapies for people with moderate to severe acne. According to the authors, carefully planned studies, using standardized outcome measures, comparing the effectiveness of common acne treatments with light therapies are needed.

Keyal et al. (2016) evaluated the evidence regarding safety and efficacy of PDT in treating acne lesions. Thirty-six clinical trials were included in the review. Twenty-four of these trials were performed to evaluate the effect of PDT in acne and 12 trials were performed to compare the effect of PDT with light or laser alone therapy. Among 24 trials that used PDT only, 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 6 and 12. Safety was assessed through physical exam, vital signs, laboratory evaluations, and physician and patient reporting of AEs. A reduction of at least two grades in IGA scale severity was demonstrated in 51.7% of patients at week 12. Furthermore, at week 12, subjects with a baseline IGA grade of 3 (moderate) demonstrated a success rate (2 or greater grade drop) of 45.3% whereas patients with a baseline IGA grade of 4 (severe) demonstrated a success rate of 61.1%. Acne inflammatory lesion counts confirmed these results, with a reduction of at least 40% of lesions in 81.6% of treated hemi-faces after 12 weeks. Treatment was considered as safe and well tolerated, with no serious AEs and no patient discontinuation from the study from any AE. The authors concluded that the BioPhotonic System comprised of LED blue-light phototherapy was efficacious and safe, with a sustained clinical response at 12 weeks for the management of moderate to severe facial inflammatory acne. According to the authors, study limitations include the absence of an established active acne topical agent as a control group. Another limitation of the study is that most included patients were female, so the results mostly apply to this population.

Mohamed et al. (2016) compared the clinical efficacy of intense pulsed light (IPL) versus 1,064 long-pulsed Nd:YAG in treatment of facial AV. Seventy-four patients were enrolled in this prospective, split-face, RCT. All participants received 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

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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 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 18-27 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 5 weeks of treatment. Comparing the effects of both therapies, BP produced better results than IPL. The difference in the results was statistically significant at the midpoint of the study. However, this difference was insignificant at the end of study.

Karsai et al. (2010) assessed the efficacy of adjuvant PDL treatment when combined with a proven topical treatment (C/BPO). Eighty patients were randomized in a 1:2 ratio to receive C/BPO alone or in combination with PDL treatment. Patients were evaluated at baseline and at 2 and 4 weeks after initial treatment. Both groups showed a significant improvement during observation, but there was no significant or otherwise appreciable difference between treatment modalities as far as the extent of improvement was concerned. Patients with more severe findings at baseline had a greater benefit from either therapy regimen. The authors concluded that their findings do not support the concept of a substantial benefit of PDL treatment in AC.

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, 1450 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/1319 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

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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 1064-nm neodymium-doped:yttrium aluminium 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 consisted of eight Nd:YAG 1064 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 1064 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 1064-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.

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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 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 1064-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 1064-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 1723 patients and 4278 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 1064-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 1064 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.

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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 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 4 monthly treatments with follow-up sessions at 1 month (visit 5, short-term) and 3 months (visit 6, long-term) after the last treatment. The participants were randomly assigned split face and received LPAL plus low-fluence Nd:YAG on one side of their face and PDL on the contralateral side of their face. The erythema index (EI) was measured at every visit with skin analysis systems, and two independent dermatologists evaluated digital photographs for five-point global aesthetic improvement scale (GAIS). The authors reported that the EI significantly decreased on both treated sides at their one-month (5^{th} visit) evaluation and that three months after the 4^{th} treatment (on their 6^{th} visit), the reduction in the EI was well maintained on both sides. When the authors compared the improvement in EI between the two groups, the percentage reduction in the EI on the LPAL-treated side was not inferior to the PDL-treated side through the 6^{th} visit. They also reported that the GAIS and patient satisfaction were comparable between LPAL and PDL sides and did not show any significant difference. Limitations of the study include the small size of the participant population, the single-center design, the uncertainty around how much each wavelength contributed to reducing the erythema in rosacea with the use of the dual-wavelength laser device. The authors concluded that the study showed that the decrease in EI in the treatment of rosacea was comparable between PDL and LPAL and that LPAL could be a promising alternative treatment option for rosacea.

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Badawi et al. (2020) conducted a study to evaluate the efficacy and safety of fractional ablative 2940 nm Er:YAG laser. The study included 16 patients with a mean age of 57.8 years who had mild to moderate rhinophyma for two to 15 years. Only one patient experienced a recurrence of the condition in the 6-month follow-up period. The authors concluded that the use of Er:YAG laser in this study demonstrated efficacy of the tool for treatment of mild to moderate rhinophyma with a rapid and pain-free recovery period. They noted that the study was limited by the lack of histopathological examination to rule out coexisting pathology and to demonstrate histopathological improvement of the treated area. They concluded that further research is needed to confirm their findings and to optimize laser settings and number of treatment sessions.

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

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

In a randomized, single-blinded, comparative study, Seo et al. (2016) compared the effectiveness of the dual wavelength long-pulsed 755 nm alexandrite/1,064 nm neodymium: yttrium-aluminum-garnet laser (LPAN) with that of 585 nm PDL for rosacea. Erythema index was measured by spectrophotometer, and digital photographs were evaluated by consultant dermatologists for physician's global assessment. Subjective satisfaction surveys and AEs were recorded. Forty-nine subjects with rosacea were enrolled in the study and 12 dropped out. Full face received four consecutive monthly treatments with LPAN or PDL, followed-up for 6 months after the last treatment. There were no significant differences between LPAN and PDL in the mean reduction of the erythema index, improvement of physician's global assessment, and subject-rated treatment satisfaction. PDL showed more adverse effects including vesicles than LPAN. No other serious or permanent AEs were observed in both treatments. The authors concluded that both LPAN and PDL may be effective and safe treatments for rosacea. According to the authors, there are several limitations in the general application of the study findings. First, as with all studies comparing 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

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general lack of high-quality studies. Almost all the reviewed studies were limited by the number of patients enrolled (usually < 100) and by the length of follow-up (typically ≤ 6 months). Long-term outcome analysis is needed. Additionally, the wide variety of IPL devices, device settings, patient demographic characteristics, and user expertise detracted from a completely homogeneous assessment of the data. According to the authors, further large-scale, high-quality studies are needed to optimally delineate exact treatment parameters for specific diseases.

In a split-face, double-blind RCT, Alam et al. (2013) compared the effectiveness of microsecond 1064 nm Nd:YAG laser with non-purpuragenic 595 nm PDL for diffuse facial erythema or erythematotelangiectatic rosacea (ETR). Bilateral cheeks received 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 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 CO2 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 carbon dioxide laser are well-established, reliable procedures for rhinophymaplasty that preserve the underlying sebaceous gland fundi allowing spontaneous re-epithelialization without scarring with similar outcomes and high patient satisfaction. According to the authors, the CO2 laser is more capital intensive and results in higher fees compared with the simpler cold blade tangential excision. The authors state that the ease of use, accuracy and precision of laser treatment is not justified by the increased costs. According to the authors, the disadvantage of the deep tissue laser penetration is that the laser may generate high thermal energy with resultant damage to the dermis and adnexa, with the associated risks of scarring, poor texture, and pigmentation modifications.

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

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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 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 repigmenting 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 repigmentation 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 repigmentation 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. Repigmentation percentages were evaluated after 30, 90, and 180 days. The authors reported that the efficacy (measured by repigmentation 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 repigmentation percentage of 40% at three months and 65% at six months while the patients in Group B reported a median repigmentation 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 repigmentation results compared to the use of Tacrolimus alone in pediatric patients with vitiligo.

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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 repigmenting 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% repigmentation. The authors reported that an excellent response (75% - 100% repigmentation) 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 participants responded with at least 50% repigmentation. 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 repigmentation. 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 repigmenting efficacy of both EL and TUVB devices in vitiligo and that targeted phototherapy with EL demonstrated better repigmenting 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 multi-center, 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. Repigmentation 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 repigmentation 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 repigmentation, and that the 308-nm EL and 311-nm NB-UVB–treated sides obtained 25% repigmentation 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 repigmentation 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

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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 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 August 29, 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 August 29, 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 August 29, 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 August 29, 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 August 29, 2024)

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Policy History/Revision Information

Date	Summary of Changes
01/01/2025	**Coverage Rationale** • 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**

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Date	Summary of Changes
	• Updated *Description of Services, Clinical Evidence, FDA*, and *References* sections to reflect the most current information • Archived previous policy version CSNCT0337.03

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