Light and Laser Therapy

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➲ Instructions for Use

Table of Contents **Page**

Application 1
Coverage Rationale 1
Medical Records Documentation Used for Reviews 2
Applicable Codes 2
Description of Services 3
Clinical Evidence 4
U.S. Food and Drug Administration 26
References 26
Policy History/Revision Information 30
Instructions for Use 30

Related Commercial/Individual Exchange Policies

- Cosmetic and Reconstructive Procedures
- Outpatient Surgical Procedures – Site of Service

Community Plan Policy

- Light and Laser Therapy

Application

UnitedHealthcare Commercial

This Medical Policy applies to UnitedHealthcare Commercial benefit plans.

UnitedHealthcare Individual Exchange

This Medical Policy applies to Individual Exchange benefit plans.

Coverage Rationale

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

- Port-wine stains
- Cutaneous hemangioma/hemangiomata

Laser hair removal is proven and medically necessary for the treatment of pilonidal sinus disease that has been or is being treated with surgery for control of hair regrowth.

Fractional ablative laser fenestration [e.g., carbon dioxide (CO_2) laser, erbium:yttrium-aluminum garnet (Er:YAG) laser] of hypertrophic burn scars is proven and medically necessary when both of the following criteria are met:

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

Light and laser therapy, including but not limited to intense pulsed light, light phototherapy, photodynamic therapy, neodymium:yttrium-aluminum garnet (Nd:YAG), and pulsed dye laser, is unproven and not medically necessary for treating the following due to insufficient evidence of efficacy:

- Acne vulgaris
- Onychomycosis
- Rhinophyma
- Rosacea

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Medical Records Documentation Used for Reviews

Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. Medical records documentation may be required to assess whether the member meets the clinical criteria for coverage but does not guarantee coverage of the service requested; refer to the guidelines titled Medical Records Documentation Used for Reviews.

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Listing of a code in this policy does not imply that the service described by the code is a covered or non-covered health service. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other policies and guidelines may apply.

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

CPT Code	Description
Cutaneous Vascular Lesion	
17106	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
17107	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); 10.0 to 50.0 sq cm
17108	Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq cm
Hypertrophic Burn Scars	
0479T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; first 100 cm2 or part thereof, or 1% of body surface area of infants and children
0480T	Fractional ablative laser fenestration of burn and traumatic scars for functional improvement; each additional 100 cm2, or each additional 1% of body surface area of infants and children, or part thereof (List separately in addition to code for primary procedure)
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue
Laser Hair Removal	
17999	Unlisted procedure, skin, mucous membrane and subcutaneous tissue

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Diagnosis Code	Description
Cutaneous Vascular Lesion	
D18.00	Hemangioma unspecified site
D18.01	Hemangioma of skin and subcutaneous tissue
I78.0	Hereditary hemorrhagic telangiectasia
I78.1	Nevus, non-neoplastic
Q82.5	Congenital non-neoplastic nevus
Q85.89	Other phakomatoses, not elsewhere classified
Hypertrophic Burn Scars	
L90.5	Scar conditions and fibrosis of skin
L91.0	Hypertrophic scar
Laser Hair Removal	
L05.01	Pilonidal cyst with abscess
L05.02	Pilonidal sinus with abscess
L05.91	Pilonidal cyst without abscess
L05.92	Pilonidal sinus without abscess

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Description of Services

Acne Vulgaris

Acne vulgaris is a common skin condition that is associated with obstruction and inflammation of the hair follicle and sebaceous glands. This may result in the formation of comedones, papules, pustules, nodules, and cysts. Acne is a multifactorial inflammatory disease, and the current understanding of acne pathogenesis is continuously evolving (Zaenglein et al., 2016). Light and laser therapies are being considered to treat acne. Light therapy is defined as exposure to nonionizing radiation for therapeutic benefit. It can include the use of phototherapy, intense pulsed light, and photodynamic therapy. Photodynamic therapy is the use of visible light, in addition to a topical application of a photosensitizer, such as 5-aminolevulinic acid (ALA) or methyl aminolevulinate (MAL). Laser types that are being studied to treat acne include near-infrared laser, pulsed dye laser (PDL), long-PDL, argon laser, smooth beam laser, and diode laser.

Hypertrophic Burn Scars

Hypertrophic burn scars result from an abnormal response in 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 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, onychomycosis 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 or laser hair depilation has been found to be effective as an adjunct or alternative to surgery. Although the condition was originally thought to be congenital in nature and secondary to abnormal skin in the gluteal cleft, the current widely accepted theory describes the origin of pilonidal disease as an acquired condition that is intimately related to the presence of hair in the cleft (Steele et al., 2013).

Port-Wine Stains and Hemangiomata

Port-wine stains (PWSs) are a type of vascular lesion that involves 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 PWSs and hemangiomas. The flashlamp-pumped 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 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 that primarily affects 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

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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 the treatment of the signs and symptoms associated with rosacea, including PDL, high-energy 532-nm pulse potassium titanyl phosphate laser, and a variety of intense pulsed light sources.

Rhinophyma is a disfiguring condition of the external nose that is characterized by tissue hypertrophy, dilated follicles, and irregular nodular overgrowth. The etiology of rhinophyma remains unknown; however, rhinophyma typically appears in the later stages of rosacea and forms gradually over the 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.

Clinical Evidence

Port-Wine Stains and Hemangiomata

Huang et al. (2026) conducted a prospective, self-controlled, paired trial that enrolled 34 participants (24 females, 10 males; aged 1 month to 56 years) with port-wine stains (PWSs) at a single hospital in China between January and December 2024. Each individual lesion was divided into two matched areas (A and B), with area A randomized to receive combined sequential picosecond laser (PSL) plus pulsed dye laser (PDL) and area B treated with PDL alone, using the same treatment frequency and duration. Efficacy was evaluated by standardized photographs, dermoscopy, and reflectance confocal microscopy that assessed lesion clearance, vascular density, and vessel diameter, while individual satisfaction and adverse events were also recorded. Both PDL monotherapy and PSL + PDL resulted in visible lesion improvement. However, the combination therapy consistently demonstrated superior efficacy. Quantitatively, the PSL + PDL group achieved significantly greater visual improvement scores (4.00 ±0.89 vs 3.03 ±1.11; $p < 0.0001$) and greater lesion area reduction (3.54% ±1.17% vs 1.68% ±1.49%; $p < 0.01$). Dermoscopic findings confirmed a greater reduction in vascular density with combination therapy, and reflectance confocal microscopy showed significantly smaller vessel diameters (0.14 ±0.02 mm vs 0.20 ±0.05 mm; $p < 0.05$) and lower vascular density (1.13 ±0.69 vs 2.44 ±1.12 vessels/mm^2; $p < 0.01$), corresponding to greater percentage reductions in both parameters compared with PDL alone. Safety profiles were favorable and comparable between groups. Individual satisfaction was significantly higher with PSL + PDL, with a greater proportion reporting significant improvement and fewer reporting only slight improvement ($p < 0.05$). The authors concluded that sequential PSL + PDL therapy was significantly superior to conventional PDL monotherapy for PWSs, demonstrated effective and safe outcomes, and represents a promising therapeutic alternative for clinical use. The study is limited by its small sample size (n = 34), which restricts the precision of effect estimates and limits the ability to detect rare adverse events. The single-center design and lack of diversity in individual characteristics further constrain generalizability, highlighting the need for larger, multicenter, randomized trials across varied skin types and lesion presentations. The absence of long-term follow-up prevents assessment of the durability of treatment outcomes. Additionally, the study did not include a PSL-only arm or evaluate reversed treatment sequencing (PDL followed by PSL), which precluded determination of the independent effects of PSL and the impact of treatment order.

Chaple Gil et al. (2025) conducted a systematic review that evaluated the efficacy and safety of laser therapies for infantile hemangiomas (IHs) across 20 clinical studies that included 2,856 individuals. Eligible studies involved infants who were diagnosed with IHs that required treatment and included randomized controlled trials (RCTs), prospective cohorts, and retrospective observational studies that assessed laser monotherapy or combination therapy with pharmacological agents such as propranolol or timolol. The interventions comprised PDL, neodymium:yttrium-aluminum garnet (Nd:YAG), diode laser, carbon dioxide (CO_2) laser, and intense pulsed light (IPL), which were compared across modalities and combination regimens, with outcomes of lesion regression, treatment duration, recurrence, and adverse effects. Due to the heterogeneity in study designs and protocols, a qualitative synthesis using descriptive statistics was performed. Complete resolution was defined by clinical examination through visual assessment and palpation of lesion flattening and color normalization, with some studies using ultrasound or Doppler imaging to confirm vascular regression. The primary findings showed that PDL at 595 nm achieved up to 85% improvement for superficial hemangiomas, while Nd:YAG at 1,064 nm reached up to 87.57% regression for deeper lesions; combination therapies with β-blockers yielded faster lesion resolution and lower recurrence rates. Laser therapy for IHs is effective and safe, particularly when combined with propranolol or timolol, resulting in superior lesion regression, shorter treatment duration, and lower recurrence rates than monotherapy. This review is limited by the substantial heterogeneity in study designs, laser parameters, and outcome measures, which precluded direct comparisons and meta-analysis. The absence of standardized treatment protocols and generally short follow-up periods further restrict conclusions regarding optimal therapy and long-term outcomes. Future research should prioritize large, multicenter RCTs that use standardized laser parameters, alongside integration of advanced imaging to guide treatment. Investigation of combination therapies and development of consensus-based clinical guidelines are also needed to improve consistency and long-term efficacy of care.

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Hashemi et al. (2025) conducted a systematic review of the safety and efficacy of 595-nm wavelength PDL for the treatment of pediatric port-wine birthmarks (PWBs) and IHs. The review included 33 studies, with 7,725 total individuals (5,692 with IHs and 2,033 with PWBs). Overall, 26 of the studies focused exclusively on the treatment of PWB, five focused exclusively on the treatment of IH, and two included both individuals who were treated for PWB and individuals who were treated for IH. All studies were published in English, had at least 10 individuals who were treated with PDL, and included only pediatric individuals (persons who were aged 21 years or younger) at the time of their diagnosis or treatment. The studies were conducted in the United States, United Kingdom, Europe, and Asia. Nine of the studies were assessed to have a level of evidence of IV, 11 to have a level of evidence of III, and 13 to have a level of evidence of II. The authors reported that only 16 of the 2,033 individuals (0.8%) with PWB and 11 of the 5,692 individuals (0.2%) with IH reported permanent adverse effects (scarring, keloids, or permanent pigmentation change), with no reports of blindness or other serious injury. The authors also reported that good, excellent, or complete clearance after PDL (on average or in greater than 50% of individuals) was reported in 17 of 19 studies (89%) and all seven of the studies (100%) for IH. The authors concluded that there is an extensive body of evidence that supports the safety and efficacy of the use of 595-nm PDL as a treatment option for early intervention in the pediatric population with PWB or IH and that its success in the treatment of PWB has made PDL the gold standard, as it significantly improves outcomes and prevents or reduces complications that are associated with untreated PWB. Limitations of the systematic review include the heterogeneous array of study designs, treatment settings, populations of individuals, and outcome measures that may limit the ability to consolidate findings across studies. The review is also limited by the wide range of sample sizes that made comparison of results between studies challenging and the potential for publication bias that may lead to disproportionate representation of positive results.

Shi et al. (2023) conducted a systematic review and meta-analysis that evaluated the safety of PDL therapy for treating PWSs; complications that were reported in 65 studies (14 RCTs, 27 nonrandomized controlled studies, and 24 observational studies) were reviewed, including 6,537 individuals (mean age range, 3.2 weeks to 39 years) who were diagnosed with PWSs and treated with PDL. Four of the studies included individuals who were less than 1 year of age, while the other 61 studies included individuals who were over 1 year old. The authors reported that the overall pooled frequency of purpura was 98.3% (reported in 12 studies), of edema was 97.6% (10 studies), of crusting was 21.5% (21 studies), of blistering was 8.7% (27 studies), of hyperpigmentation was 12.8% (58 studies), of hypopigmentation was 0.9% (57 studies), and of scarring was 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 that involved individuals with a dark skin type showed a higher complication rate for hyperpigmentation, hypopigmentation, and scarring than studies that involved individuals with a light skin type; they also stated that an increased complication rate was also noted in studies with a mean age above 1 year, when PDL treatment was performed on the torso or limb, in studies with a mean number of treatments that was greater than three, and when the spot size was 5 millimeters. The authors concluded that effective protective measures after treatment were very important for preventing scar formation and that overall, PDL treatment of PWSs showed a high level of safety and low chance of causing long-term complications. Limitations of this study include the wide variation in the quality of the included studies, incomplete data for baseline treatment in some studies, inability to perform a meta-regression analysis, and inability to determine the potential factors affecting the probability of complications. The Faurschou et al. (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 PWSs. The study included 129 patients (70.54% male; median age at start of treatment, 16 years) who had received a total of 4,141 laser treatment sessions (median of 49 sessions; IQR, 27-66 sessions), with PDL having been used in 88.63% of the sessions, followed by 1,064 long-pulse Nd:YAG (4.01%) and 532 long-pulse Nd:YAG (2.63%). The authors performed a 25-year double-blinded, retrospective chart review of patients who were diagnosed with PWSs, 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 in the group defined as 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 III, and a greater number of treatments, while factors that were associated with ≤ 50% improvement were hypertrophic PWSs, 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 that were rendered. The authors concluded that vascular lasers were a promising treatment for PWSs and that multiple treatment sessions were required to achieve optimal results. The study is limited by the retrospective single-center design, use of various forms of laser therapy, combined types of lasers, and heterogeneity of the treatment protocols.

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Wang et al. (2023) conducted a systematic review and meta-analysis to assess the safety and efficacy of photodynamic therapy (PDT) for PWSs. The review included 26 studies (three RCTs and 23 cohort studies) in which PDT was administered to 3,034 individuals with PWSs. The authors noted that the characteristics of the treatment protocols varied between studies, as there were three different kinds of photosensitizers used, along with variation between the number of treatments (1-8.2 treatments), therapy interval (4 weeks to 2-3 months), and follow-up period (2 months to 5 years). The authors concluded that PDT is a safe and effective treatment for PWSs. In their evaluation of bias risk, the authors determined that 23 of 26 nonrandomized experiments were of poor quality and that the three RCTs were of moderate quality. The authors reported that 51.5% of the individuals achieved a 60% improvement after treatment with PDT and that 20.5% of individuals achieved a > 75% improvement [GRADE (Grading of Recommendations Assessment, Development, and Evaluation) 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.

Fei et al. (2020) conducted a systematic review and network meta-analysis that reviewed the efficacy and adverse effects of different therapies to address IH. They evaluated 30 RCTs that included more than 20 different therapeutic regimens and a combined 2,123 children who were diagnosed with IH. The authors completed a network meta-analysis 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 that PDL was most commonly the first choice of vascular laser therapy and mostly reported and applied in IH laser therapy. They also found that a longer pulse has higher efficiency due to its advantage in transdermal depth. One of their findings was that the treatment regimen of PDL plus oral propranolol had the lowest incidence of adverse events. The study concluded that a combination of β-blockers and lasers might be the first-line treatment of IHs and that a longer PDL is preferred. The authors acknowledged that the quality of some indirect comparisons was low according to GRADE and that the study individuals were not grouped by sex. The authors recommended additional well-designed RCTs to confirm their findings.

Clinical Practice Guidelines

American Academy of Pediatrics (AAP)

AAP clinical practice guidelines on the management of IHs 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 β-blocker therapy, laser approaches are used less frequently (Krowchuk et al., 2019).

Pilonidal Sinus Disease

Jarrin Lopez et al. (2026) conducted a retrospective, descriptive, single-arm cohort study that evaluated patients who were aged 14 to 89 years and underwent operative treatment of pilonidal sinus disease with adjunctive laser hair removal; patients were obtained from one health system with multiple hospitals and outpatient clinics in California between 2012 and 2024. Inclusion required surgical excision with adjunctive laser hair removal, with exclusion of those who were managed nonoperatively or outside the age range. Overall, 168 patients were included, with 101 undergoing pilocystectomy and 67 undergoing Bascom flap closure; the mean ages were 23 and 24 years, respectively, and most patients were male. Laser hair removal was performed using alexandrite or Nd:YAG lasers that covered at least 2 cm around the surgical scar. The primary outcomes were repeat procedures, 30-day surgical site infections, and unplanned clinic visits, defined, respectively, as any subsequent incision and drainage or re-excision, any documented infection within 30 days, and any outpatient visit outside routine follow-up. Across the cohort, repeat procedure, surgical site infection, and unplanned visit rates were 16.7%, 14.4%, and 39.3%, respectively; Bascom flap closure had fewer repeat procedures (10.4% vs 20.8%) and unplanned visits (33.8% vs 43.6%) than pilocystectomy, with similar infection rates (14.9% vs 14.0%). Exploratory bivariable logistic regression found no significant associations between sex or body mass index and outcomes, with odds ratios for repeat procedure in the pilocystectomy group of 1.21 (95% CI, 0.35-4.23; p = 0.76) for sex and 0.94 (95% CI, 0.84-1.06; p = 0.31) for body mass index. The authors concluded that Bascom flap closure was associated with fewer repeat procedures and unplanned clinic visits than pilocystectomy, while surgical site infection rates were similar, and that the findings provide descriptive benchmarks for outcomes in routine practice but do not establish the independent benefit of laser hair removal. There are limitations, including the descriptive nature of the findings, which do not estimate the independent effect of laser hair removal, and the absence of a non–laser hair removal control group. The retrospective single-arm design prevents causal inference regarding the effect of adjunctive laser hair removal. Recurrence-related outcomes are inconsistently defined in the pilonidal sinus disease literature, and some variables such as disease severity, adherence to postoperative care, and degree of hair reduction were not available in a standardized form due to the real-world electronic health record–based design.

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Bergus et al. (2024b) conducted a single-center RCT to investigate the heterogeneity of treatment effects of laser epilation (LE) in preventing pilonidal disease (PD) recurrence. The study included 280 participants who were aged between 11 and 21 years with pilonidal sinus disease and randomized to receive either gluteal cleft LE and standard of care (improved hygiene and mechanical or chemical depilation; n = 131) or standard care alone (n = 149). The median age in both groups was 17 years, and non-Hispanic White race/ethnicity was most common (75%); 40% of participants were obese, and 73.6% had only one prior episode of disease before trial enrollment, with 16.8% having required prior surgical excision. Private health insurance was most common (67.1%), and the annual household income exceeded $100,000 in 43.6% of participants. One-year follow-up data were available for 96 participants in the laser group and 134 participants in the standard care group. The authors noted that due to shutdowns during the COVID-19 pandemic, laser treatment appointments were temporarily halted, resulting in a group of 15 participants who were randomly assigned and enrolled in the LE group; these participants never started treatments and no longer wanted to participate when elective procedure suspensions were lifted. The authors reported that there were no significant differences in treatment effects based on sex, body mass index, previous disease, prior surgical excision, or annual household income. The authors reported that the recurrence rate among non-Hispanic White participants was 4% (three of 75) with laser treatment and 31.6% (31 of 98) with standard care vs 38.9% (seven of 18) with laser treatment and 38.2% (13 of 34) with standard care among all other racial/ethnic groups. They reported that the recurrence rates among privately insured participants were 4.0% (three of 75) with laser treatment and 33.3% (29 of 87) with standard care vs 36.8% (seven of 19) with laser treatment and 29.7% (11 of 37) with standard care in those with public insurance. The authors concluded that the effectiveness of LE to reduce PD recurrence rates may vary based on race and ethnicity and insurance type, and they recommended additional studies to investigate this potential heterogeneity of treatment effects. Limitations of the study include the single-center design, which affects the generalizability to other practices using different methods for PD management; additionally, the exploratory analysis of additional factors that may contribute to the heterogeneity of treatment effects, including race/ethnicity and insurance type, was limited by small sample sizes for several categories. The study is limited by the lack of control for differences in skin color and race/ethnicity and lack of longer-term follow-up, which may have identified delayed episodes of recurrence that occurred more than 1 year after treatment. Finally, the study is limited by the loss to follow-up and missing data for the primary and secondary outcomes, which may have been exacerbated by the COVID-19 pandemic.

Muscat et al. (2024) conducted a systematic review and meta-analysis of three RCTs to determine the effectiveness of laser hair removal in preventing pilonidal sinus disease recurrence. The three RCTs included a total of 448 pediatric and adult individuals who underwent either laser hair removal or conventional hair removal (shaving or depilatory cream) for the prevention of recurrence of pilonidal sinus disease; the individuals were followed up for at least 1 year post treatment. The authors reported that there was a significant difference on odds ratio analysis (odds ratio = 0.319 with a lower bound of 0.160; upper bound of 0.636; and p = 0.001) that showed a lower incidence of recurrence following laser hair epilation compared with conventional hair removal techniques. Limitations of this systematic review and meta-analysis include the small number of RCTs available for inclusion (all of which were at a risk of bias due to lack of blinding), heterogeneity of the study designs, and inclusion of only articles that were written in the English language. (Minecci et al., 2024, Demircan et al., 2015, and Ghnnam et al., 2011, were included in this systematic review and meta-analysis and previously included in this policy.)

Salimi-Jazi et al. (2023) investigated the number of laser sessions required to achieve certain amounts of hair reduction and the correlation with recurrence of PD in a single-center, retrospective, observational study. All the 198 study patients underwent LE with or without additional surgical procedures such as trephination or incision and drainage. The mean age at the time of the first LE treatment was 18 $\pm$3.6 years. Data collected from each patient included demographics, Fitzpatrick skin type classification (I-VI), hair color (light or dark), hair thickness (fine, medium, or thick), number of LE sessions, any procedures done (incision and drainage, trephination of pilonidal pits, or re-excision), follow-up period, and any recurrences. There were 21 patients who had skin type I/II, 156 with skin type III/IV, and 21 with skin type V/VI. Overall, 47 patients had light-colored hair, and 151 had dark-colored hair; 29 patients had fine hair, 65 had medium-sized hair, and 40 had thick hair. Surgical procedures were done in 176 patients, with 44 requiring incision and drainage and 132 undergoing trephinations. The authors reported that during the study period and compared with the patients' initial hair amount, 188 patients (95%) reached 20% hair reduction, 138 (70%) reached 50%, 78 (40%) reached 75%, and 38 (19%) reached 90%. Overall, the mean number of laser sessions that reached 20%, 50%, 75%, and 90% hair reduction was 2.6, 4.3, 6.6, and 7.8 sessions, respectively. The recurrence rate in their study was 6%. The authors stated that more mean LE sessions correlated with a higher percentage of hair reduction regardless of the patients' hair and skin characteristics. The authors also concluded that increasing the amount of hair reduction correlated with a lower chance of recurrence and that targeting 75% hair reduction can be a clinically relevant treatment goal to reduce recurrence. Limitations include the retrospective single-center design, lack of a control group, low number of patients with certain skin and hair types, and low recurrence rate, which may not provide enough power to detect all the factors that could affect the recurrence of PD. The authors concluded that individuals with dark-colored and thick hair require more LE sessions to achieve a certain degree of hair reduction and are more likely to experience PD recurrence.

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Check et al. (2022) conducted a prospective case series in 78 participants who had mild PD and were treated at a dedicated pilonidal care clinic with a treatment protocol aimed at source control, with improved hygiene, excision of pilonidal pits, and laser ablation of midline follicles to prevent new pits from forming, with no nidus resection. The mean age was 16.3 years, and 55% of the population was female. All participants were started on an enhanced hygiene routine at their first clinic visit and were offered pit excision when there was minimal active inflammation in their crease; participants were also offered laser follicle ablation if hirsute. Overall, 73 participants underwent LE, and 68 underwent pit excision. For participants with multiple, closely located pits, sequential alternating pit excision sessions were scheduled to improve wound healing, and laser ablations were continued until resolution of crease hirsutism. Repeat visits were scheduled every 6 to 8 weeks until all pit wounds were healed and crease follicles were ablated, with a minimum follow-up period of 1 year. The authors reported that 77 of the 78 participants had resolution of their PD after a mean of 3 ±2.5 LEs and 1.3 ±1 pit excisions during 4 ±2 clinic visits over a duration of 30 ±19 weeks. Overall, 67 of the 68 participants who underwent pit excision were resolved, as were nine participants who underwent LE alone and one with hygiene alone. One participant continued to receive care for asymptomatic, new pits. The authors concluded that treating mild PD with improved hygiene, pit excision, and LE resulted in minimal morbidity and no activity restrictions. Limitations of the study include the single-center design, high rate of attrition of almost 25%, and lack of follow-up beyond 1 year.

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

Halleran et al. (2018) conducted a systematic review of published literature that analyzed laser hair depilation (LHD) in PD to determine its effect on disease recurrence. Overall, 35 published studies were included. Of these, 28 studies were retrospective, and seven were prospective. There were five comparative studies: two retrospective, one prospective observational, and two RCTs. The number of individuals who were included in each study ranged from one to 86, and individuals received between one and 11 laser treatments. The PD recurrence rate after LHD ranged from 0% to 28% at a mean follow-up that ranged from 6 months to 5 years across studies. Four of the five studies that included a comparative group demonstrated a decreased recurrence rate compared with the nonlaser cohort. The reviewers concluded that LHD is a promising therapy in the management of PD. However, the literature that is published to date is heterogeneous and has limited generalizability. Additional research is needed to determine the effectiveness of LHD to prevent PD recurrence.

Lopez et al. (2017) conducted a prospective, single-arm, pilot trial of LHD to the natal cleft to assess the safety and tolerability of the procedure in 13 adolescents with PD. Each participant received outpatient LHD treatment every 4 weeks, with a goal of five total treatments. Follow-up tolerability was measured after each treatment by obtaining the Likert scale, participant-reported scores, and pain scores immediately after laser treatment and every 6 hours post treatment for the first 24 hours. The primary end point was tolerability and safety, defined as pain scores that were consistently less than 4 and absence of deep second-degree burns during the 24-hour posttreatment period. The secondary end point was disease recurrence at 1 year. Overall, 12 participants completed five LHD sessions, and one participant completed four sessions. There was 100% tolerability of treatments, with no occurrence of second-degree burns. No participant was unable to complete a treatment session because of discomfort. Significantly diminished hair growth was noted after three treatments. All 13 participants were recurrence free at a median follow-up of 13 months post treatment initiation. Researchers concluded that LHD is safe and well tolerated in adolescents with PD and may be effective at decreasing PD recurrence. A prospective RCT is planned to determine the effectiveness of LHD compared with that of chemical/mechanical depilation methods in preventing PD recurrence.

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Clinical Practice Guidelines

American Society of Colon and Rectal Surgeons (ASCRS)

The ASCRS guidelines for managing PD state that elimination of hair from the gluteal cleft and surrounding skin, by shaving or LE, may be used for both acute and chronic PD in the absence of abscess as a primary or adjunct treatment measure. The guideline advises that treatment usually includes one to four treatments of hair removal, cyst curettage, and phenol application into the cyst and tracts for complete resolution of the condition. A weak recommendation was made by the ASCRS for laser hair removal for treating PD based on an insufficient level and quality of evidence to assess the significance or to provide a general recommendation for this approach (Johnson et al., 2019).

Italian Society of Colorectal Surgery (SICCR)

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

Hypertrophic Burn Scars

Betar et al. (2025) conducted a longitudinal cohort study in which clinicians and individuals reported outcomes after ablative fractional CO_2 laser ($AFCO_2L$); additionally, the safety and factors that influenced the outcomes were evaluated. The study included 47 adults (median age, 32 years; median burn total body surface area, 35%) who had hypertrophic burn scars, were treated with $AFCO_2L$ treatments over approximately 12 months, and completed follow-up appointments, with data available for analysis. Original burn treatment included split-thickness skin grafting in 43 of the individuals (92%), with seven (15%) experiencing delayed healing of non–operatively managed areas of burned skin that resulted in hypertrophic scarring. Overall, 14 individuals (30%) underwent one treatment, 22 (47%) underwent two treatments, 10 (21%) underwent three treatments, and one (2%) underwent four treatments with $AFCO_2L$, with laser treatments spaced approximately 3 months apart; 21 (45%) received treatment to the face and/or neck, 28 (60%) to the upper limb, 19 (40%) to the torso, and 11 (23%) to the lower limb. The median time between burn injury and the first $AFCO_2L$ treatment was 607 days. Some individuals underwent concurrent surgical scar revisionary procedures at the time of laser. No other laser types were used in conjunction with $AFCO_2L$, and laser-facilitated topical drug delivery of corticosteroids was used in all individuals immediately after laser, as were medicated postoperative dressings. The outcomes were ultrasound scar thickness, the Patient and Observer Scar Assessment Scale (POSAS), and the Brisbane Burn Scar Impact Profile, measured at baseline and 3, 6, and 12 months after the first $AFCO_2L$ treatment. The authors reported that statistically significant improvements between baseline and the 12-month follow-up occurred in scar thickness (21% reduction in the mean thickness from baseline) and in all POSAS and Brisbane Burn Scar Impact Profile subscores and that most improvements remained when accounting for total body surface area, Fitzpatrick skin type, scar maturity, and body area treated. The authors also stated that individuals reported transient symptoms after 61 of 89 treatments (69%), but that infection or delayed wound healing occurred after only four of 89 treatments (4%). The authors concluded that the study supported safety and improved clinician- and individual-reported outcomes in adults who were undergoing $AFCO_2L$ for the treatment of hypertrophic burn scars. Limitations of the study include the heterogeneity of prior and concurrent treatments received, location of the burns treated, number of $AFCO_2L$ treatments received, lack of 12-month data for 30% of the included individuals, and necessity for additional treatments in two-thirds of the cohort after the final study assessment, as this may indicate worsening of hypertrophic scar symptoms over time after $AFCO_2L$ treatment.

Goel et al. (2025) conducted a prospective, interventional, double-blinded, parallel, two-arm RCT using a split-scar technique to compare the erbium:yttrium-aluminum garnet (Er:YAG) laser with intralesional triamcinolone vs Er:YAG laser alone in 34 participants who were aged 12 to 50 years and had postburn hypertrophic scars. Each participant received four treatment sessions at 4-week intervals, with follow-up 2 months after the last session. The primary outcome was percentage reduction in scar thickness from baseline to the fifth follow-up, which was measured objectively with vernier calipers, while the secondary assessments included the University of North Carolina scar scale (pruritus, paresthesia, pliability, and participant satisfaction). A greater than 75% reduction in scar thickness was achieved in 52.9% of the combination group vs 26.5% of the laser-only group (chi-square = 7.939; $p = 0.047$). The combination group also had significantly better improvement in pruritus ($p = 0.001$), paresthesia ($p = 0.006$), and pliability ($p = 0.045$), with higher participant satisfaction scores. The authors concluded that combination treatment with the Er:YAG laser and intralesional corticosteroid was more efficacious than laser monotherapy in improving scar thickness, pruritus, paresthesia, pliability, and participant satisfaction. A small, single-center sample that has short follow-up limits statistical power and generalizability. The split-scar design introduces nonindependence and potential treatment contamination, while blinding and subjective outcomes increase the risk of bias. Additionally, limited reporting of randomization methods, attrition, and noninferiority margin justification constrains confidence in the findings.

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An ECRI (2025) Clinical Evidence Assessment evaluated fractional CO_2 laser ablation for reducing burn scars from three systematic reviews, six RCTs, and four nonrandomized comparative studies. The findings indicate that fractional CO_2 laser ablation is a safe and effective treatment for hypertrophic burn scars, with improvements demonstrated on the Vancouver Scar Scale (VSS) and POSAS. Quality-of-life, pain, and pruritus outcomes were reported less frequently but also demonstrated favorable effects with fractional CO_2 laser treatment. Interpretation is constrained by heterogeneity in the populations of individuals (age, burn size, and scar age), treatment protocols, outcomes, follow-up duration, and study settings. Additionally, several trials used intrapatient randomization and assigned scars rather than individuals to treatment groups.

Bergus et al. (2024a) conducted a single-center retrospective study that included 99 pediatric patients (55.6% male; 53.5% White; 31.3% Black; 8.1% multiracial; 7.0% another/unknown race) with hypertrophic burn scars who were treated with 322 fractional CO_2 laser treatments [with (45.5%) or without (54.5%) PDL] to evaluate the treatment's effectiveness on burn wounds when stratified by specific body region and prior burn wound therapy. The median age at the time of burn injury was 4.0 years, and the median age at the time of the first laser treatment was 7.1 years. The source of burn injury was flame in 43 patients (43.4%), scald injuries in 45 patients (45.5%), chemical burns in six patients (6.1%), and contact burns in five patients (5.1%). There was a total of 230 burn wounds that developed hypertrophic scars and underwent fractional CO_2 laser treatments among the 99 patients. Most wounds were partial thickness only (48.3%), while 39.6% were full thickness only, and 12.2% had both partial- and full-thickness components. The initial treatment included dermal substrate, followed by autografting in 55.2% of patients, while 29.6% were treated with dermal substrate alone, and 9.1% underwent autografting alone. Patients were offered fractional CO_2 laser therapy for hypertrophic burn scars with functional limitations, including medically intractable pruritus, and PDL treatments were added for patients with any score of greater than 0 for the vascularity subcomponent of the modified VSS (mVSS). Following laser application in each session, all patients received steroid treatment with triamcinolone through intradermal injection (40 mg/mL) and/or topical application (0.1%) based on the height score noted on the mVSS subcomponent score. Patients were empirically scheduled for three consecutive treatments approximately 4 to 8 weeks apart and then were reassessed in the clinic. After the third treatment, additional treatments were recommended based on clinical response. The authors reported that most body regions showed improvement in mVSS scores with laser treatment and that mVSS scores improved significantly with treatment to the anterior trunk, arms, and legs; however, there was no significant difference in mVSS scores after laser treatment of scars on the head, neck, posterior trunk, genitalia/buttocks, hands, or feet. The authors also reported that the mVSS components of pigmentation and vascularity, as well as total score, improved significantly when all body regions were averaged; a significant difference in height was observed after laser treatment in wounds with an initial scar height of greater than 5 millimeters. Patients who were treated after flame or scald injuries were reported to have significant improvement in mVSS scores after laser treatment, although there was no significant difference in mVSS scores in those who were treated after chemical or contact burns. The authors concluded that knowing the variable effectiveness of laser treatment in pediatric burn scars is useful when counseling individuals and families prior to treatment. Limitations of the study include the retrospective single-center design, heterogeneity of types of burns and locations of injury, inclusion of treatment with and without PDL, and subjectivity of the mVSS assessment tool. Additional limitations include the lack of consistency in completing all laser treatment sessions due to limitations in operating room availability during the COVID-19 pandemic; individual family scheduling constraints; and small number of patients in several subgroups that were compared.

Chen et al. (2024) conducted a meta-analysis of 10 studies, with a total of 413 children (59% male), to evaluate and explore the efficacy of CO_2 fractional laser in treating postburn hypertrophic scars in children. The studies included seven retrospective studies (n = 323 individuals), two RCTs (n = 53 individuals), and one prospective cohort study (n = 49 individuals). The authors reported that the meta-analysis showed that the average VSS after surgery was significantly lower than that before surgery and that after CO_2 fractional laser, pigmentation, pliability, vascularity, and height were improved compared with before treatment. The authors also reported that the average visual analog scale (VAS) after surgery was significantly lower than that before surgery and that both POSAS-Observer and POSAS-Patient were significantly lower than those before surgery. The authors concluded that CO_2 fractional laser is beneficial to the recovery of hypertrophic scar after burn in children and can effectively improve the scar symptoms and signs in children. (This study is included in Patel et al., 2019, which was previously included in this policy, and ECRI, 2025).

Ma et al. (2024) conducted a systematic review and meta-analysis to investigate the effects of factors such as scar age, type of laser, and laser treatment interval on burn scar outcomes in children. Seven studies (two RCTs, three prospective studies, and two retrospective studies) were included in the meta-analysis, with a total of 467 children (average age, 10 years; male-to-female ratio of 1:1). Ablative CO_2 lasers were used in three studies (n = 254 individuals), PDL was used in one study (n = 13 individuals), nonablative laser (NAL; Nd:YAG laser 1,064 nm) was used in one study (n = 50 individuals), and a combination of PDL and ablative was used in two studies (n = 150 individuals). The authors reported that laser therapy significantly improved the VSS/POSAS, vascularity, pliability, pigmentation, and scar height of burn scars and that subgroup analyses were performed due to the significant heterogeneity that was found between the

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studies. The subgroup analysis was reported by the authors to show that early laser therapy (provided less than 12 months from the date of injury) significantly improved VSS/POSAS scores and vascularity compared with latent therapy (provided more than 12 months from date of injury). The authors also reported that the NAL was most effective and significantly reduced the VSS/POSAS, vascularity, pliability, and scar height outcomes compared with ablative, PDL, and a combination of ablative and PDL treatments. Additionally, they reported that shorter treatment intervals of less than 4 weeks significantly reduced the VSS/POSAS and scar height outcomes compared with longer intervals of 4 to 6 weeks. The authors concluded that the efficacy of laser therapy in the pediatric population was influenced by scar age, type of laser, and interval between laser therapy application; however, significant heterogeneity in the studies suggests the need to explore other confounding factors that influence burn scar outcomes after laser therapy. Limitations of this systematic review and meta-analysis include the significant heterogeneity among the included studies, treatment protocols, and populations in each study, as well as the lack of a control group, which makes it difficult to draw conclusions. (This study is included in Patel et al., 2019, which was previously included in this policy.)

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

Hayes (2023; updated 2024) directed their Heath Technology Assessment on the use of fractional laser treatment (FLT) to address functional impairment in individuals with a history of burn and traumatic scars and reviewed four published studies (including one prospective pretest-posttest study, one RCT, and two retrospective pretest-posttest studies) that included the use of a CO_2 laser to deliver FLT. Their 2025 review identified five additional studies (two RCTs, one pretest-post test study, and two retrospective chart reviews); however, there were no changes to the current Hayes ratings. The overall quality of evidence for FLT for functional impairment secondary to burn or traumatic scars was rated as low, while the quality of evidence for FLT for functional impairment secondary to keloid scars due to burns or trauma or for the use of lasers other than CO_2 lasers was rated as very low due to the lack of available studies. The report concluded that the overall low-quality body of evidence suggests that ablative FLT with CO_2 appears to be reasonably safe and may result in statistically significant improvements in function in individuals with functional impairments that are caused by hypertrophic scarring from burns and/or trauma; however, it was unclear whether FLT consistently led to clinically important improvements or whether it provided benefits beyond conventional scar care.

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

Staubach et al. (2023) conducted a study in their institution of 77 children with scars after thermal injury. These were treated at least three times or more by CO_2 laser or in combination with PDL and followed up for 10 years. Prior to treatment, scar texture and elasticity were objectively determined by a skin elasticity analysis system, and for the subjective evaluation, a questionnaire was given to the individuals or their parents. Additional assessment tools were the

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POSAS and VSS. The results showed a statistically significant improvement in elasticity in all scars of any age after each laser treatment. In addition, a significant correlation was found between the number of laser treatments and an increase in elasticity. The assessments of scars after one or more laser sessions by the observer, as well as the individual, showed a decreasing score in all categories, with an increase in the number of laser therapies. The VSS score also improved significantly after each laser session. The mean score before treatment was around 7, and after the first laser session, it was already below 6. Subjectively, the results showed that 96% of individuals or their parents were satisfied with the laser therapy, and 90% wished to repeat the procedure. The authors concluded that this study demonstrates objective improvements in elasticity following laser treatment, with no adverse effects reported. This study is limited by a small number of individuals in a single institution. Furthermore, there was a lack of randomization with controls to compare the results to those with standards of care for scars. Additionally, treatment was combined with PDL, making it difficult to assess the results of CO_2 laser treatment. Further high-quality research is needed to validate these findings.

Buhalog et al. (2021), in a systematic review, evaluated the existing literature regarding ablative fractional lasers for the treatment of hypertrophic scars. Overall, 23 retrospective cohort RCTs, quasi-RCTs, observational prospective cohort studies, or case series were included. The studies included five or more individuals who had hypertrophic scars that were incurred from burns and related trauma. In total, 859 individuals were included and underwent a total of 2,433 laser treatments. The majority of the studies used the VSS as a primary outcome measure. The POSAS was the next most common. Other objective outcome measures included ultrasound for scar height/thickness, instruments to assess scar pliability and color, quartiles of overall improvement, histological evaluation of collagen and elastin architecture and content, immunohistochemistry for growth factors and other mediators, and range of motion. The subjective outcome tools that were used included quality-of-life indices, scales of pruritus, and individual willingness to pay for treatment. The results showed that of the studies that reported the overall VSS and POSAS, there was a statistically significant improvement in all outcomes measured with these tools. Furthermore, 22 of the 23 studies documented statistically significant and meaningful improvements in nearly all outcome measures. Laser treatments were well tolerated in general, with minor adverse effects such as skin discoloration, pain and swelling, blistering, erythema, infection, and ulceration, which typically resolved by the final follow-up visit. The authors concluded that ablative fractional lasers are emerging as an alternative scar management treatment between conservative measures and surgical management. Treatment is well tolerated and has a relatively low incidence of minor adverse events. Future studies should prioritize standardized protocols that include assessments of function and quality of life. This study is limited by the significant heterogeneity and high risk of bias of the included studies.

Choi et al. (2021) conducted a systematic review and meta-analysis of 15 published studies to evaluate the efficacy of fractional CO_2 lasers in treating burn scars; the authors reported that laser therapy alone yielded statistically significant improvements in scar profiles, with few reported adverse effects. The analysis included a total of 778 individuals, with a median age of 22 years. All the studies used $AFCO_2L$, with a median of 2.5 treatments per individual over a range of 1 to 3 months between treatments. Indications for treatment included large, symptomatic, hypertrophic scars, with minimum treated areas, ranging from 20 cm^2 to 100 cm^2. Response to therapy was measured in most of the studies with the VSS (12 studies) and POSAS (nine studies). The authors reported that individuals who were treated with $AFCO_2L$ had meaningful, rapid improvement in burn scars, as demonstrated with statistically significant improvements in validated scar scores in their analysis. The authors concluded that $AFCO_2L$ laser therapy is safe and effective for the treatment of burn scars.

Issler-Fisher et al. (2021) conducted a retrospective, single-center, case-control study to look at the impact of $AFCO_2L$ treatment compared with that of conventional conservative treatment. The study included 187 patients, 167 in the $AFCO_2L$ treatment group and 20 in a control cohort, whose $AFCO_2L$ treatment was delayed due to access-to-care issues. Age, gender, ethnicity, Fitzpatrick skin type, smoking status, comorbidities, and prolonged wound healing showed no significant differences between the two study groups. The median time since injury in the two groups was 16 months, and the time between initial assessment and the median follow-up was approximately 5 months. The patients in the control cohort received simple, conservative care (silicone, pressure garments, etc.) and then were reassessed prior to undergoing $AFCO_2L$. The authors reported a significant reduction in scar thickness in the $AFCO_2L$ group but no significant improvement in the control group; they reported that subjective parameters had decreased significantly in the $AFCO_2L$ group but had worsened at the follow-up in untreated groups. The complication rate was 2.9%. The authors concluded that $AFCO_2L$ was an effective and safe treatment modality for burn scars, with improvement in thickness, symptoms, and quality of life in burn survivors compared with conventional scar treatment. Limitations include the retrospective single-center study design and risk of subjective bias due to the observational aspect of data collection tools that were used.

Peng et al. (2021) conducted a meta-analysis of 20 articles that comprised RCTs, cohort, case-control, and comparative studies to assess the efficacy and safety of fractional CO_2 for the treatment of burn scars. The results showed significant improvements in the VSS, as well as the patient and observer scores of the POSAS. Scar thickness measured by

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ultrasound was significantly reduced, as was pigmentation, elasticity, vascularity, pliability, and height of the scar. However, scar firmness, as measured by cutometer, was not reduced. Only five studies reported adverse side effects that included hypo-/hyperpigmentation, discoloration, erythema, infection, bleeding, and swelling, and none of the side effects were severe. The authors concluded that treatment with fractional CO_2 significantly improves the appearance and morphology of burn scars that were evaluated using the VSS and POSAS by both individuals and the physician, as well as ultrasound-evaluated scar thickness. Limitations of this study include substantial heterogeneity of the studies, which included multiple countries; range of follow-up; and different treatment session protocols, which limit generalizability. Additionally, most of the included studies had a small number of individuals. Furthermore, the influence of other variables such as burn size and severity, hypertrophic scarring, and laser delivery parameters were not assessed. Well-designed, larger studies are needed to validate these findings. [This study is included in the Clinical Evidence Assessment by ECRI (2025).]

Osterhoff et al. (2021) conducted a systematic review regarding the outcomes of erythema, pigmentation, height, and pliability of the different laser systems on hypertrophic scarring and keloid. Thirteen studies, with 16 study arms, that reported outcomes on scar characteristics were identified. Three studies reported outcomes on characteristics with a CO_2 laser system in a fractional setting. In erythema, a mean 56% improvement was seen, above the overall mean of 37%. Regarding pigmentation, a mean reduction of 36% was reported above the overall mean of 8%. Height was improved by 46%, where the overall mean was 37%. A mean 59% improvement was reported in pliability, above the 47% overall mean. Reduced pliability corresponds with concerns of contractures, and a clinically relevant improvement was seen in most study arms, with a slight advantage to the CO_2 10,600-nm laser system. This systematic review suggests that the ablative fractional laser systems (CO_2 10,600 nm and Er:YAG 2,940 nm) yielded the most improvement across all scar characteristics. Most studies scored the scars by only using observed subjective clinical improvement. Future RCTs and prospective studies that include a methodologically strong design, well-defined scar characteristics, and standardized, validated outcome measurements are needed to confirm this conclusion.

Zhang et al. (2021) conducted a meta-analysis to evaluate the effectiveness of the fractional CO_2 laser for the treatment of burn scars. Overall, 14 studies were included, and all except one retrospective study were prospective in design and were single-arm evaluations. There was no significant publication bias identified. The results showed significant improvements in the VSS, POSAS, and Scar Assessment Scale scores after treatment, especially with regard to pigmentation, vascularity, pliability, and height of scar. Pain and pruritus also improved with this treatment. However, scar thickness decreased statistically nonsignificantly, and no improvement could be observed in scar firmness or elasticity, although lesser data were available to evaluate scar thickness, firmness, and elasticity. This meta-analysis found that one to four sessions of treatment of burn scars with fractional CO_2 laser is associated with significantly improved outcomes.

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

Clinical Practice Guidelines

International Society for Burn Injuries (ISBI)

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

Acne Vulgaris

There is insufficient evidence to recommend the use of light and laser therapy for the treatment of acne vulgaris. Studies that evaluate light and laser therapy for acne typically are short term; lack controls or include study participants who 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.

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Bakircioglu et al. (2026) conducted a prospective, comparative, open-label, nonrandomized clinical study at a single dermatology center to evaluate the efficacy, treatment response, and safety of cold atmospheric plasma shower vs 585-nm Q-switch laser in mild to moderate acne vulgaris. Enrolled was a total of 47 participants who were diagnosed with mild to moderate acne vulgaris and aged 18 years or older; participants were allocated to either the plasma shower (n = 24) or 585-nm Q-switch laser (n = 23) groups based on clinical decision and participant preference, with only those completing two treatment sessions and all follow-up visits being included in the final analysis. Exclusion criteria included dermatologic conditions with Koebner phenomenon, psychiatric issues, unrealistic expectations, photosensitivity, malignant lesions, active erosion or keloids, recent sunburn or tanned skin, and any acne treatments before or during the study. Acne severity was measured using the Global Acne Grading System at baseline, week 2, and week 4. Statistical analyses included Shapiro-Wilk testing for normality, independent t tests for between-group comparisons, and repeated-measures ANOVA (analysis of variance; with Greenhouse-Geisser correction if needed) to assess treatment effects over time, with Bonferroni-adjusted post hoc tests. Changes from baseline to week 4 and their associated factors were further evaluated using t tests and multiple linear regression, with significance set at a p value of < 0.05. Global Acne Grading System scores decreased significantly over time in both groups ($p < 0.001$), with a significant time-by-treatment interaction ($p = 0.003$), indicating different response patterns; the plasma shower group had greater improvement by week 4, with a significantly larger reduction in scores ($p = 0.007$; Cohen d $= 0.82$) and higher percentage improvement (42.5% vs 32.2%). Multivariable analysis showed that higher baseline severity and plasma shower treatment independently predicted greater improvement, while age, gender, and skin type were not significant; clinically, plasma therapy more effectively reduced inflammatory lesions, whereas Q-switched laser primarily improved erythema. The authors concluded that cold atmospheric plasma was more effective than the 585-nm Q-switch laser for mild to moderate acne vulgaris, particularly in reducing active inflammatory lesions, while the Q-switch laser was effective for postinflammatory erythema. Key limitations include a small, single-center, nonrandomized sample, with short follow-up, which increases the risk of bias and limits generalizability. Findings were further constrained by the lack of objective erythema measures and absence of evaluation of combination therapy effects.

Olugbade et al. (2025) conducted a retrospective cohort study to evaluate the efficacy and tolerability of a 650-ms laser for the treatment of mild to severe facial acne vulgaris. The study included the records of 225 patients (aged 14-61 years; 89% female; 41% Caucasian; 38% African American; 9% Asian; 3% Hispanic; 9% of other races) with mild to severe facial acne vulgaris. Acne severity was assessed at each visit using the Investigator Global Assessment (IGA) scale, during which patients were assigned an initial IGA score from the clinical photos that were taken immediately before the laser procedure, with each score independently reviewed and agreed on by at least two investigators. A variety of topical medications were reportedly used in conjunction with the laser treatment, with the most frequent being benzoyl peroxide (BPO), adapalene, azelaic acid, and minocycline, while oral medications included antibiotics (56.4%) and hormone-modulating therapies (17.3%). Additionally, a variety of nonlaser procedures (such as chemical peels and extractions) were used by some patients. The authors reported that patients required a median of three treatments (range, 0-10 treatments) to achieve clearance and that clearance was achieved in 108 patients (48%) 6 months after the laser procedure; adverse effects were limited to acne flare-ups and dryness. The authors also reported that treatment with isotretinoin was not required in 80% of the patients and that the median IGA score was 1.0 (almost clear) at the 6-month follow-up visit. Also, for most IGA-rated parameters, differences between White patients and patients with skin of color were not statistically significant according to the authors. While no serious adverse events were observed during the study, nonserious adverse events were recorded in 210 of the patients' records, including acne flare-up (55.7%) and dryness (13.3%), as well as erythema (1.9%), edema (0.5%), and itchiness (1%). The authors concluded that the 650-ms, 1,064-nm Nd:YAG laser provided a safe and efficacious treatment for mild to severe acne in White patients and those with skin of color. Limitations of the study include the retrospective single-center design, lack of a comparator, and heterogeneity of other therapies used in conjunction with the laser therapy.

Akuffo-Addo et al. (2024) conducted a systematic review to assess the efficacy of visible light in acne treatment, including 35 studies that represented 1,185 individuals (mean age, 23.7 years; 63% female) with acne vulgaris. The average number of treatment sessions was 22 (range, 1-112 sessions), and the mean treatment duration was 7 weeks. Mild to moderate acne severity was reported in 80% of the 532 individuals with available data, with 94% of the 1,105 individuals having acne on the face and 6% having acne on the trunk. All individuals had a washout period from topical or oral antiacne medications, and all but one individual was healthy without comorbidities. No concurrent treatments were received during treatment with visible light. The authors reported that overall, 92% of individuals achieved partial remission of their acne lesions using visible light therapy; of them, 46% experienced a reduction of 0% to 50%, 33% experienced a 51% to 74% reduction, and 12% experienced a 75% to 99% reduction in acne lesions. Overall, the average total lesion count improved by 43% at week 4 compared with baseline. The authors also reported that blue light (used in approximately 64% of the cases) emerged as the predominant treatment modality, as 95% of those who were treated with blue light experienced a partial clearance of acne lesions (44% had a reduction of 0% to 50%, 42% had a reduction of 51% to 74%, and 9% had a reduction of 75% to 99%). Other light modalities used in the studies included a combination of blue and red light (24%; n = 281/1,185) and red light (8%; n = 98/1,185). According to the authors, treated individuals

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responded, on average, within a period of 4 weeks and commonly reported side effects, including skin irritation and erythema. The authors concluded that their systematic review highlighted the potential of visible light therapy in acne treatment and recommended head-to-head studies to compare the efficacy of visible light compared with that of existing therapies. Limitations of the study include the (1) limited sample sizes and lack of comparators between light therapy and various multimodal treatments for acne in most of the included studies; (2) diverse treatment outcomes that were reported; and (3) the different scales, which made it difficult to synthesize the findings. Other limitations include the lack of standardized assessment methods and lack of detailed information regarding dosage, mean power, and proximity to light, which affects the ability to reproduce the experiments.

Fan et al. (2024) conducted a single-center, prospective, split-face, nonrandomized controlled trial to compare blue laser–mediated PDT (BL-PDT) and 630 ±10-nm red light–emitting diode-mediated PDT (RL-PDT) aminolevulinic acid (ALA)–based PDT for moderate and severe acne vulgaris. The study included 16 participants (14 male; mean age, 22.1 years) with moderate to severe acne vulgaris, with 15 of the participants completing the treatment regimen and attending all follow-up visits. There was no significant difference in IGA scores observed between the right and left faces at baseline. All participants underwent BL-PDT on the left side of the face and RL-PDT on the right side, which were delivered three times per week at 2-week intervals, with follow-up continuing through 2 weeks after the final treatment. The authors reported that the average rates of improvement at the 2-week follow-up after the final treatment were 48% for total acne, 63% for inflammatory lesions, and 30.0% for noninflammatory lesions in the BL-PDT group and 42.2%, 58.1%, and 27.5%, respectively, in the RL-PDT group. The authors also reported that the IGA scores in the two groups decreased by 1.8 points in the BL-PDT group and 1.7 points in the RL-PDT group and that the IGA success rate was 53.3% in both groups. There were no significant differences between the BL-PDT and RL-PDT groups that were reported by the authors in any measure of effectiveness; however, the BL-PDT group had more severe adverse effects, especially in pain and hyperpigmentation. The authors concluded that BL-PDT and RL-PDT have similar effects in moderate to severe acne vulgaris and were particularly effective for inflammatory acne lesions and that participants who received RL-PDT benefited from milder adverse effects. Limitations of the study include the small number of participants, single-center design, homogeneity of the study population, and short follow-up period.

Ashmawy et al. (2024) conducted a single-center, prospective, right-left comparative study that included 40 participants (age, 17-22 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 vs that of topical erythromycin 2% cream. All participants were evaluated using the Global Acne Severity (GEA) Scale and Indian Acne Association grading scale, with photographs before each session and at each follow-up, and for participant satisfaction. Participants were instructed not to use any other treatment for acne during laser therapy and for 3 months after the last session. Each participant underwent split-face treatment: one side with eight treatments (twice per week for 4 weeks) of a low-level, continuous infrared diode laser and the other side with topical erythromycin 2% twice daily. Participants were evaluated at the start of each session, 2 weeks after the end of the sessions, and 3 months after the end of treatment. Three blinded dermatologists recorded the percentage of improvement in each participant after completion of the treatment by comparing digital photographs before starting treatment and 2 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 that were treated with laser showed better results than the antibiotic side. The authors also reported that the laser side showed less relapses than the antibiotic side and that participants were more satisfied with laser treatment due to minimal side effects and less relapse. The authors concluded that low-level, continuous infrared diode laser that was rendered in eight treatment sessions represented a cheap, safe, effective, noninvasive therapeutic option for acne vulgaris. Limitations of the study include the single-center design; small, homogeneous study population; and short follow-up period.

Hammoda et al. (2023) conducted a prospective, single-center, comparative study that assessed the efficacy of fractional CO_2 laser vs that of Nd:YAG laser for acne vulgaris therapy. Overall, 30 adult women who were between 18 and 24 years of age and experiencing mild to severe acne according to the GEA scale were enrolled. Each participant underwent both types of laser treatments in a randomized, split-face design at 14-day intervals for four sessions. The primary assessment was performed by counting the number of acne lesions at 1 month after the last session, while the secondary assessment included severity grading by the GEA scale, acne lesion improvement percentage, and participant satisfaction. The authors reported that after treatment (4 weeks after the final session), a statistically significant reduction in mean inflammatory count in the fractional CO_2 side compared with the Nd:YAG side was detected, but no statistically significant difference was found in mean noninflammatory acne count between both therapeutic modalities; however, after 3 months' follow-up, the fractional CO_2 showed a statistically significant reduction in mean inflammatory and noninflammatory lesions compared with Nd:YAG. The authors concluded that fractional CO_2 and Nd:YAG lasers were both safe, tolerable, and highly effective therapeutic options for acne, although fractional CO_2 laser had a higher percentage of improvement and participant satisfaction than long-pulsed Nd:YAG. The study is limited by the small sample size, single-center design, short follow-up period, and homogeneity of the study population.

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Mavranezouli et al. (2022) conducted a systematic review and network meta-analysis of topical pharmacological, oral pharmacological, physical, and combined treatments for acne vulgaris 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), PDT [i.e., therapy comprising a light source, such as red light, blue light, or daylight, and a photosensitizing chemical, such as 5-ALA or methyl aminolevulinate (MAL)], 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 a high risk of bias and 36 of the 67 RCTs for moderate to severe acne being at a 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 compared with placebo. The authors stated that for moderate to severe acne, topical treatment combinations, oral antibiotics combined with topical treatments, oral isotretinoin, and PDT were most effective for moderate to severe acne. The authors concluded that further research is needed for chemical peels and photochemical and photodynamic therapies, as the evidence is promising but limited.

Sapra et al. (2022) conducted a single-center, retrospective chart review in 187 patients with acne vulgaris (acne) to evaluate the safety of concomitant therapy of oral isotretinoin with NAL, specifically multiplex PDL and Nd:YAG. The average age of the patient was 21.4 years (12-47 years), and all patients had a clinical 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 6 months after starting their isotretinoin therapy in 6.4% (n = 12) of the patients, 53.5% (n = 100) of patients only during the usage of isotretinoin, and 40.1% (n = 75) both during and after isotretinoin usage. The authors reported that 31.6% of patients experienced mild side effects while on concomitant isotretinoin and NAL therapy. Of those with available effectiveness data, 99.2% of patients (n = 132) achieved an IGA score of clear or almost clear, which was maintained up until the most recent follow-up. The mean length of follow-up was 902.7 days, with a minimum of 63 and a maximum of 3,520 days. The authors concluded that their study demonstrated the safety of performing NAL therapies during and immediately after isotretinoin use. Limitations of the study include the single-center retrospective design; lack of standardized lesion count assessments; and lack of a control group.

Piccolo et al. (2022) performed a prospective study to assess the efficacy, safety, and reproducibility of a novel IPL protocol as a monotherapy in the treatment of acne of the chest and back. Overall, 50 participants who ranged from 18 to 40 years of age (mean age, 23.8 years), had Fitzpatrick skin types II to III, and moderate papulopustular acne on the chest and back were retrospectively enrolled from the authors' private practice centers. Four IPL sessions at 2-week intervals in each participant were performed. Per the authors, an excellent outcome was achieved in 50% of the participants, and a good outcome was achieved in 35% of the participants. Participants 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 that provided good aesthetic and therapeutic results in 85% of treated participants. Further research that includes RCTs is needed to validate these findings.

ECRI (2021) evaluated the application of PDT for the treatment of acne vulgaris, psoriasis, sebaceous gland hyperplasia, and refractory nongenital warts in a Clinical Evidence Assessment of PDT for benign skin lesions. Their review of PDT for acne vulgaris comprised a review of one published systematic review with meta-analysis of 13 RCTs. ECRI stated that the meta-analysis showed that PDT improved inflammatory acne, with a mean percentage reduction in the inflammatory lesion count and total effective response; however, ECRI noted that the evidence is 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.

Lu et al. (2020) assessed the safety and efficiency of IPL therapy in the treatment of acne vulgaris in a meta-analysis. The authors reviewed eight RCTs, including the Mohamed et al. (2016) study 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 individuals and concluded that (1) IPL is not as efficient as other supplementary therapies, as the results of the IPL group's mean percentage reduction of inflammatory acne lesions was poorer than that in the control group that was treated with pulsed dye therapy, and that (2) the efficiency of IPL was poor among African and Asian populations. They also found that the difference in efficiency between IPL and 1,064-nm Nd:YAG was not statistically significant. The authors noted that there are limitations to the meta-analysis, including the heterogeneities among the studies, which included the use of various filters for the IPL system, various pulse modes, number of treatment

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sessions, and the interval period. Other limitations that they identified include a lack of studies that had a large sample size and the single-center design of all the studies that were included in the meta-analysis.

Scott et al. (2019) performed a systematic review and meta-analysis of studies that assessed 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. The mean difference in the mean number of noninflammatory (open and closed comedones) and inflammatory lesions (papules, pustules, and 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 include small sample sizes, short intervention periods, and a high risk of bias.

de Vries et al. (2018) assessed the efficacy and safety of nonpharmacological therapies in the treatment of acne vulgaris in a systematic review. 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 870-1,200 nm) and the diode laser (1,450 nm). Initially, conflicting evidence was found for PDL (585-595 nm). Circumstantial evidence was the basis for nonpharmacological therapies in the treatment of acne vulgaris, for which the authors were unable to draw clear conclusions. They concluded that these outcomes provide a first step in future research.

Boen et al. (2017) performed a systematic review of the literature for PDT used for acne and critically evaluated the studies. Overall, 69 clinical trials, four case reports, and two retrospective studies met the inclusion criteria. Seven of the studies were high quality. The most common photosensitizers that were used were 5-ALA and MAL, and both showed similar responses. Red light was the most frequently used light source, followed by IPL, and showed comparable results. Inflammatory and noninflammatory lesions both responded to treatment, with inflammatory lesions showing greater clearance in most studies. Adverse events that were associated with PDT for acne were mild and included pain on illumination and postprocedural erythema and edema. The authors indicated that this review supports PDT as an efficacious treatment for acne and that it is a good adjunctive treatment for mild to severe acne, especially in individuals 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.

Barbaric et al. (2016) conducted a Cochrane review to evaluate the effects of light treatment of different wavelengths for acne. Overall, 71 RCTs (4,211 individuals; 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. Results from a single study (n = 266; low quality of evidence) showed little or no difference in effectiveness on individuals' assessment of improvement between 20% ALA-PDT, activated by blue light, vs vehicle plus blue light, whereas another study (n = 180) of a comparison of ALA-PDT (red light) concentrations showed that 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 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 with placebo or no treatment, infrared light with no treatment, gold-microparticle suspension with vehicle, and clindamycin/BPO combined with PDL with clindamycin/BPO alone. None of these showed any clinically significant effects. Although the primary end point 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 3 months after final treatment. The authors concluded that high-quality evidence on the use of light therapies in 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, that compare the effectiveness of common acne treatments with that of light therapies are needed. Selection and performance bias was unclear in most studies. Two-thirds of studies were industry sponsored; the study authors either reported a conflict of interest, or such information was not declared, so the risk of bias was unclear.

Keyal et al. (2016) evaluated the evidence regarding the safety and efficacy of PDT in treating acne lesions. Overall, 36 clinical trials were included in the review. In total, 24 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 that of 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 a retrospective study. The authors concluded that PDT is an effective treatment modality for acne lesions. However, more

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RCTs are needed to establish standard guidelines regarding concentrations and the 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 nonresponders. Moreover, RCTs that compare 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, which is an LED blue-light phototherapy device that uses specific photoconverter chromophores in the treatment of moderate to severe acne vulgaris. Overall, 104 participants with moderate to severe acne were eligible for inclusion in the study and screened for enrollment. Of them, 98 (94%) were randomized, and 90 (92%) underwent at least one treatment session. Five participants decided to withdraw their consent before receiving the first treatment, and three participants were not treated, as the study enrollment period had ended. Efficacy was assessed through changes in acne severity using the IGA scale and inflammatory acne lesion counts, which were both evaluated against baseline at weeks 6 and 12. Safety was assessed through physical examination, vital signs, laboratory evaluations, and physician and participant reporting of adverse events. A reduction of at least two grades in IGA scale severity was demonstrated in 51.7% of participants at week 12. Furthermore, at week 12, participants with a baseline IGA grade of 3 (moderate) had a success rate (2 or greater grade drop) of 45.3%, whereas participants with a baseline IGA grade of 4 (severe) had 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 hemifaces after 12 weeks. Treatment was considered to be safe and well tolerated, with no serious adverse events and no participant discontinuation from the study from any adverse event. The authors concluded that the BioPhotonic System, which comprised 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 participants were female, so the results mostly apply to this population.

Mohamed et al. (2016) compared the clinical efficacy of IPL vs that of 1,064 long-pulsed Nd:YAG in the treatment of facial acne vulgaris. Overall, 74 participants 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-week intervals. The final assessment was made by comparison of the changes in the count of inflammatory acne lesions (inflammatory papules, pustules, nodules, and cyst) and noninflammatory 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 noninflammatory acne lesions were reduced by 18.3% and 19.3%. For both therapies, there was a significant difference in the improvement in inflammatory acne lesions compared with noninflammatory lesions. There was no significant difference in the efficacy of the two therapies in reducing the percentage of both types of acne lesion 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 the treatment of inflammatory facial acne vulgaris. Study limitations include the absence of an established standard therapy as a control group.

Clinical Practice Guidelines

National Institute for Health and Care Excellence (NICE)

The NICE guideline that addresses acne vulgaris management makes a “consider recommendation” only for PDT for people who are aged 18 years or older and have moderate to severe acne if other treatments are ineffective, not tolerated, or contraindicated. This recommendation is based on evidence from small studies that show that therapy from these light sources, with or without adding chemical or physical photosensitizer, may be effective. NICE does not make a strong recommendation due to the limited evidence when compared with pharmacological treatments. No recommendation is made for any other form of light therapy based on the committee’s conclusion that the overall quality of studies is very low with a serious risk of bias and risk of very serious imprecision. The committee states that further research is required to determine the most effective physical treatments for acne (NICE, 2021; updated 2026).

American Academy of Dermatology (AAD)

In the 2024 updated guideline on care for the management of acne vulgaris, the AAD states that the available evidence remains insufficient to develop a recommendation on the use of laser- and light-based devices [including 585- to 595-nm PDL, Nd:YAG laser, 1,450 diode laser, potassium titanyl phosphate (KTP) laser, infrared light-emitting diode, 635- to 670-nm red light, combined 420-nm blue light and 660-nm red light, 589-nm/1,319-nm laser, and IPL], microneedle radiofrequency device, or PDT with ALA for the treatment of acne. According to the AAD, RCTs that include 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 determination of which types of lesions they improve are also needed (Reynolds et al., 2024).

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Onychomycosis

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

Abdou et al. (2025) conducted an RCT in university-affiliated dermatology clinics that involved 45 participants with onychomycosis to evaluate the efficacy of combined PDT and fractional CO_2 laser treatment. Participants were randomized in a 1:1:1 ratio into three treatment arms. Group A received biweekly conventional PDT with 2% methylene blue following urea pretreatment; group B underwent fractional CO_2 laser therapy that was delivered over four sessions at 3-week intervals; and group C received combination therapy that consisted of fractional CO_2 laser immediately followed by PDT during the same session every 3 weeks. Treatment efficacy across groups was assessed at baseline and 12 weeks using clinical [Onychomycosis Severity Index (OSI)], mycological [potassium hydroxide (KOH) microscopy and culture], and participant satisfaction outcomes. The cohort had a mean age of approximately 39 years across groups, with similar age distributions and a predominance of female participants (82%). Demographic and risk factor profiles were comparable between groups, with no significant differences in risk exposures or fungal species distribution. However, disease duration varied significantly, with the combination therapy group having a longer mean duration. Onychomycosis subtypes were heterogeneous, with distal lateral subungual onychomycosis being most common. All groups had significant mycological clearance, but the combination achieved the highest fungal eradication (KOH positivity fell from 100% at baseline to 13.3% post treatment in the combined group vs 26.7% with laser alone and 40% with PDT; $p < 0.001$ for each). Only the combination arm had significant clinical improvements, including greater reduction in affected nail area ($p = 0.004$), more limited proximal spread of infection ($p = 0.003$), and markedly improved severity index scores ($p = 0.003$); neither monotherapy arm had significant changes in these measures ($p > 0.05$). Participant satisfaction was highest with combined therapy, although intergroup differences were not statistically significant ($p = 0.198$). Side effect rates were similar across all groups ($p = 0.649$), comprising mostly mild effects (e.g., transient nail discoloration or pain) that did not require discontinuation. Combined PDT with fractional CO_2 laser–assisted drug delivery appears to be a safe and more effective treatment for onychomycosis than either modality alone, resulting in improved mycological and clinical outcomes and greater satisfaction among individuals. However, a longer treatment duration may be required for complete cure, and additional research is needed to confirm long-term efficacy. Limitations include the small sample size and limited study duration, which may not adequately capture long-term outcomes. As such, further research that includes larger cohorts and extended follow-up is needed to better assess the durability of treatment effects.

García-Oreja et al. (2025) conducted a randomized controlled, parallel clinical trial at a single podiatry center in Madrid to compare diode laser combined with PDT vs daily ciclopirox 8% hydroxypropyl nail lacquer for onychomycosis. Included were adults who were aged 18 years or older and had microbiologically and polymerase chain reaction–confirmed onychomycosis to assess the primary outcome of clinical cure. Clinical cure was defined by the study as a resolution of signs and symptoms with confirmatory microbiological testing, and analyses included between-group comparisons, with p values, logistic regression (odds ratios with 95% CIs), and time to healing. Overall, 26 participants were randomized equally, with 24 completing treatment and a total of 32 nails being analyzed. The diode laser and PDT group received an eight-session treatment protocol over approximately 9 weeks, with visits every 7 days; sessions 1, 4, and 8 included combined diode laser and PDT, while the remaining sessions used diode laser alone with varying wavelengths. The ciclopirox group self-applied ciclopirox daily at home and had monthly clinic visits throughout the entire 12-month period; treatment duration was prolonged (at least 9 months) and effectively overlapped with the full follow-up period. Both groups were monitored and assessed at 3, 6, 9, and 12 months. Diode laser and PDT achieved a significantly higher clinical cure rate than ciclopirox (94.1% vs 53.3%; difference, 40.8%; $p = 0.008$), with logistic regression confirming the effect (odds ratio, 0.071; 95% CI, 0.007-0.685; $p = 0.022$), and faster healing (3.6 ±1.2 vs 9.2 ±1.6 months; $p < 0.001$). However, diode laser and PDT were associated with adverse events (subungual hematoma and blisters in 11.4%) and a 33.3% recurrence rate, whereas no adverse events or recurrences were observed with ciclopirox. The authors concluded that diode laser and PDT produced higher and faster cure rates than ciclopirox but with more adverse effects and higher recurrence. Limitations include a small sample size; single-center design, with all procedures performed by one unblinded investigator; lack of a combination-therapy arm; incomplete microbiological assessment in noncured cases; and unequal posttreatment follow-up duration between groups.

Sayed et al. (2024), in a single-center, randomized, comparative trial, compared the clinical efficacy and safety of fractional CO_2 laser combined with topical tioconazole nail solution vs those of Q-switched Nd:YAG 1,064-nm laser in the treatment of fingernail onychomycosis. The study included 13 adults (mean age, 41.6 years; 23% male), with 47 fingernails affected by onychomycosis; participants were not pregnant, did not have localized bacterial infection around the affected nail or concomitant nail disease, did not have a history of oral antifungal medication within the last 3 months, and did not use any topical antifungal medication within the last 2 weeks prior to laser treatment. Participants were

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randomly allocated 1:1 to receive either fractional CO_2 laser combined with topical tioconazole (n = 23 nails) or Q-switched Nd:YAG 1,064-nm laser (n = 24 nails) every 2 weeks for 3 months followed by a 1-month follow-up assessment. Results of the therapy were reviewed by a blinded investigator. The authors reported that the OSI score showed improvement after treatment in both study groups, from 16.27 to 10.92 in the fractional CO_2 arm and 23.13 to 22.43 in the Nd:YAG group, while the Dermatology Life Quality Index score significantly improved in both groups; however, there was no statistically significant difference between the two groups. The authors also reported that there was significant improvement in the participant satisfaction score in both groups and that mycological cure using the KOH test was detected in the CO_2 group by 44.4% and by 56.5% in the Nd:YAG group, with no significant difference between groups. The authors concluded that fractional CO_2 laser combined with topical tioconazole is more efficient in the treatment of onychomycosis than Q-switched Nd:YAG with regard to clinical improvement but that both had a comparable effect on mycological cure. The authors recommended its use as adjuvant treatment rather than alone to ensure mycological cure in onychomycosis. Limitations of the study include the single-center design, with a homogeneous population and preponderance of female participants, and the short 1-month follow-up period.

Ramzy et al. (2024) conducted a prospective, one-arm, single-center study to assess the use of 1,064-nm Nd:YAG on 213 mycotic nails (204 toenails in 30 participants and nine fingernails in three participants) in 31 adults (16 males; mean age, 53.5 ±13.1 years) to assess the safety and efficacy of laser treatment for onychomycosis. Study participants presented with mostly severe *Tricophyton rubrum*–positive (87.1%) infections, and most (61%) had a family history of onychomycosis. Comorbidities included hypertension (38.7% of participants), hyperlipidemia (35.5%), and/or diabetes (12.9%). While this was the first treatment for onychomycosis in 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 VAS, and the mycological and clinical cure rates were determined 3 months following the last treatment session with an online Scoring Clinical Index for Onychomycosis calculator. Onychomycosis was mostly calculated to be severe, with a mean Scoring Clinical Index for Onychomycosis score of 21.9 ±8.9 at baseline. All participants completed the full course of treatment, which consisted of eight Nd:YAG 1,064-nm laser treatment sessions to each affected nail once a week for 4 consecutive weeks and then once every 2 weeks for an additional 8 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 participants (12.9%), with visual improvements noted in 10 of the participants (32.3%). Limitations of the study include the one-arm single-center design, small population size, unreliability of determining mycological cure rates with superficial nail layers, short-term follow-up period, and heterogeneity of the comorbidities and previous treatments in the study population. The authors concluded that Nd:YAG 1,064-nm laser was safe and partially effective for the management of mild to moderate onychomycosis in diverse populations but was largely ineffective in addressing severe cases. The authors recommended further study of specific subsets of individuals to determine treatment parameters and studies that compare 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 individuals (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 onychomycosis. The studies included six that applied CO_2, five that used Nd:YAG, and one that 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 individuals' satisfaction rate was 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 individuals' satisfaction. Their subgroup analysis of outcome indicators (mycological cure rate and clinical effective rate) demonstrated that both CO_2 laser therapy combined with topical antifungal therapy and 1,064-nm Nd:YAG laser therapy combined with topical antifungal therapy showed better results than topical antifungal therapy alone. The authors reported that 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 shows that laser and topical antifungal agent combination therapy is effective for onychomycosis, although they recommended more large-scale and well-designed RCTs. Limitations of the study include the heterogeneity of the study designs, types of onychomycosis, severity of the disease, and duration of treatment; type, fluency, and pulse of the laser treatment; and follow-up period in the included studies, which limited the number of studies that were available for meta-analysis for each type of laser. The authors recommended that more clinical trials be conducted for a more comprehensive analysis.

Kandpal et al. (2021), in a single-center, randomized, parallel study, sought to compare the efficacy of Q-switched Nd:YAG laser as a monotherapy compared with that of itraconazole. Participants with confirmed cases of onychomycosis (finger or toenail) who had not received treatment 6 months before presentation were randomly allocated to two groups of 50 adults (age range, 20-45 years), each with participants who were well matched; no significant statistical difference in age and gender was noted between the two groups. Dermatophyte infection accounted for 66% of the participants in the

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laser group and 72% of the participants in the itraconazole group. The OSI and VAS scores were used to assess nail involvement at the start of the study, at 3 months, and at 1 year after enrollment. In the Nd:YAG group (70% male), participants with onychomycosis were treated with 12 weekly sessions of laser therapy, while the itraconazole group (74% male) received 200 mg twice daily for 1 week per month for 3 months. The authors reported that the VAS and OSI showed statistically significant improvements at 3 and 12 months in the Nd:YAG group, although the OSI was comparable in both groups at 12 months. The authors also reported that both dermatophytes and nondermatophytes responded well to laser treatment, although nondermatophytes responded better to laser. The authors concluded that Q-switched Nd:YAG laser was effective in inducing nail clearance in onychomycosis and was better than itraconazole in managing nondermatophyte onychomycosis. Limitations of the study include the single-center design, lack of measurement of the nail growth rate, use of a negative culture as a measure of the cure rate, and small sample sizes.

Han et al. (2021) conducted a meta-analysis of five RCTs, with 497 individuals with onychomycosis, to compare the efficacy and satisfaction rates of CO_2 laser therapy with those of topical agents. In 253 individuals, CO_2 laser treatments were combined with topical agents (tioconazole, luliconazole, tazarotene, clotrimazole, and lidocaine), while 161 individuals received independent topical antifungal therapy, and 50 individuals received CO_2 alone. The duration of treatment varied from 3 to 6 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 compared with topical agents alone, with low heterogeneity observed among studies. The authors also reported that mycological clearance comparison rates were also improved by combined treatments (60%) compared with topical agents (48%) and that individuals' satisfaction outcomes showed significant differences between the combined treatment group vs the group that received topical agent alone. However, no statistical significance was observed between the combined group vs the CO_2 laser treatment alone group. Finally, the authors reported that subgroup difference analyses showed no statistical significance ($p = 0.46$), which indicated similar effects for both types of CO_2 therapy used in the studies (ablative CO_2 and fractional CO_2) for onychomycosis. The authors concluded that combined therapy may exert positive effects and satisfactory safety in individuals with moderate to severe onychomycosis; however, the authors recommended more comprehensive RCTs to determine optimal combination options and appropriate dosages. The meta-analysis is limited by an unclear risk of allocation concealment in all but one study, limited number of published RCTs available for inclusion, heterogeneity of the topical agents used, types of CO_2 used and treatment courses among studies, and small sample sizes in each of the three study groups.

Foley et al. (2020) sought to assess the clinical and mycological effects of topical drugs and device-based therapies on onychomycosis in the Cochrane Database of Systematic Reviews. While the review itself included 56 studies (12,501 individuals), only three of the included studies (112 individuals) compared 1,064-nm Nd:YAG laser with no treatment or sham treatment. The authors stated that (1) they were uncertain if there is a difference in adverse events; (2) there may be little or no difference in mycological cure at 52 weeks (very low-quality evidence; two studies with 85 individuals); and (3) complete cure was not measured. The authors stated that there was not enough evidence to recommend or discourage the use of 1,064-nm Nd:YAG laser or PDT 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.

Ma et al. (2019) conducted a systematic review and meta-analysis on the curative effects and safety of laser treatment for onychomycosis, evaluating 35 published trials (five RCTs, 14 comparison studies, and 16 self-control studies) that included a total of 1,723 individuals and 4,278 infected nails. The authors stated that the included studies did not show evidence of publication bias; the risk of selective reporting was determined to be low, and 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 that the mycological cure rate of long-pulse width 1,064-nm Nd:YAG laser treatment was 71.0%; mycological cure rate of CO_2 FLT was 45.0%; and 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 treatment 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 individuals reported experiencing a tolerable mild to moderate burning sensation during laser treatment. The authors concluded that laser treatment of onychomycosis was effective and safe; however, they stated that more RCTs are necessary to verify their findings. Limitations of the study include the heterogeneity of the studies that were included, with different ages, duration of disease, and duration of follow-up.

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 individuals, to examine the evidence on the efficacy of laser treatment of onychomycosis. All trials, except two, applied 1,064-nm Nd:YAG lasers to treat onychomycosis. The authors analyzed the studies with individuals as the unit of analysis (UOA; n = 13) separately from the studies with nails as the UOA (n = 7),

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and there were two studies that used both individuals and nails as the UOA. The authors reported that when results were reported based on individuals as the UOA, mycological cure (12 trials) was achieved in 70.4% of individuals, clinical improvement (five trials) was achieved in 67.2%, and complete cure (three trials) was achieved in 7.2%, although high statistical heterogeneity was detected in all three analyses. When the authors evaluated trials using nails as the UOA, they reported that mycological cure (three trials) was 22.9%, clinical improvement (seven trials) was achieved in 56.2%, and complete cure (two trials) was achieved in 24.5%, all with significant, high heterogeneity detected. The authors concluded that the current level of evidence is limited, and, with high heterogeneity, it was difficult to assess the true efficacy of laser treatment for onychomycosis. The authors recommended that larger RCTs, with well-defined methodology, be conducted. Limitations include the heterogeneity of the study designs and treatment parameters; short follow-up period (1-12 months); variability in definitions of outcome, choice of analysis, and diagnostic techniques; lack of information in 17 trials for the clinical severity and duration of onychomycosis; and small number of RCTs that were available for inclusion.

Rosacea and Rhinophyma

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

Chen et al. (2026) conducted a retrospective single-center study in 120 patients with erythematotelangiectatic rosacea (ETR) who completed phototherapy between June 2019 and June 2024. Eligible patients had completed prescribed treatment courses and follow-ups, used no systemic medications, and followed standardized skin care, while those with comorbid skin diseases, severe systemic illness, or recent photoelectric therapy were excluded. Patients were assigned to 585-nm PDL (two sessions at 6-week intervals), M22 590 IPL (three sessions at 4-week intervals), or multisource 3DEEP radiofrequency (six sessions at 2-week intervals), with uniform 12-week posttreatment assessment. Efficacy was measured using the Clinician Erythema Assessment (CEA), Patient Self-Assessment (PSA), and Rosacea-Specific Quality of Life (RosaQoL) scales, and safety outcomes included pain and adverse reactions. Statistical analyses used paired t tests for intragroup and ANOVA or chi-square tests for intergroup comparisons ($p < 0.05$). All 120 patients completed treatment, and significant within-group improvements were observed in CEA, PSA, and RosaQoL scores ($p < 0.001$), with total effective rates of 57.50% for PDL, 45.00% for M22 590, and 67.50% for radiofrequency ($p = 0.126$). Between-group differences in CEA ($F = 4.573$; $p = 0.012$), PSA ($F = 3.365$; $p = 0.038$), and RosaQoL ($F = 12.635$; $p < 0.001$) changes were statistically significant, while adverse reaction incidence differed markedly ($F = 79.955$; $p < 0.001$), favoring radiofrequency for tolerability. The prespecified secondary end points included pain score and incidence of specific adverse reactions such as purpura, erythema, edema, and pigmentation. The authors concluded that all three modalities were effective and safe for treating ETR, with comparable efficacy but superior safety and minimal pain for radiofrequency, which supports its use in individuals prioritizing comfort and low downtime. Key limitations include the absence of follow-up beyond 12 weeks, which limits assessment of long-term durability and recurrence. The single-center design and modest sample size further restrict generalizability. The use of a multidimensional evaluation framework (CEA, PSA, and RosaQoL) partially mitigates the limitations of single-parameter assessments. Potential residual confounding that is related to baseline severity, vessel morphology, and parameter titration may have influenced comparative outcomes, although the radiofrequency group had numerically greater reductions but no significant difference in overall effectiveness.

Nguyen et al. (2026) conducted a systematic review and network meta-analysis of RCTs that evaluated the efficacy and safety of laser- and energy-based treatments for rosacea. Eligible studies included full-text RCTs that evaluated any laser- or energy-based treatments for rosacea, including those that target facial telangiectasias. Studies on rhinophyma, ocular rosacea, or Morbus Morbihan were excluded as distinct subtypes. Trials that assessed only a single intervention were treated as one-arm studies and excluded from the quantitative analysis. Overall, 25 trials, comprising 843 individuals (mean age, 46.9 years; 66.3% female), were included, with interventions such as PDL, radiofrequency microneedling, IPL, and combination therapies. Most trials evaluated persistent erythema [76% (n = 690)] and telangiectasia [88% (n = 784)]. Data were standardized to a VAS that ranged from 1 to 5 to measure individuals' satisfaction, erythema, and telangiectasia, and analyses used random-effects models within an additive network meta-analysis framework. Radiofrequency microneedling was significantly more effective than PDL in individuals' satisfaction (mean difference, -1.32; 95% CI, -1.89 to -0.76) and erythema (mean difference, -1.44; 95% CI, -1.96 to -0.91), while oxymetazoline plus PDL was superior for telangiectasia (mean difference, -0.58; 95% CI, -1.03 to -0.14). Adverse events and discontinuation rates were comparable across treatments, and the prespecified secondary end points included short-term adverse events such as crusts, swelling, and erythema. The authors concluded that the systematic review and network meta-analysis provided a comprehensive evaluation of laser- and energy-based devices for rosacea, with results interpreted cautiously due to a generally unclear to high risk of bias. Key limitations include the unclear or high risk of performance and selection

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bias due to the nature of device-based treatments, as well as insufficient reporting of blinding and randomization processes. There are limitations related to data quality, including incomplete data, that prevented a meta-analysis of adverse events. The study has limitations in scope, as the included trials did not assess the influence of skin type, age, or rosacea severity, and the relatively small sample size limited detailed sub-analyses. Generalizability is limited by the exclusive focus on RCTs, lack of long-term follow-up data that are needed to assess durability and recurrence, and variability among laser- and energy-based devices that may affect efficacy and safety. (Park et al., 2022, which was previously cited in this policy, is included in this systematic review.)

Nganzeu et al. (2025) conducted a retrospective, single-center case series in seven patients with melanated skin and moderate to severe rhinophyma who were treated with CO_2 laser excision to evaluate the efficacy of this treatment approach in melanated skin without increased risk of scarring. The study population included five adults who identified as Native American and two who identified as non-White Hispanic; 71.4% were male, with an age range of 43 to 77 years. Three patients underwent one procedure, three underwent two procedures, and one underwent three procedures over a 3-year period. Four of the patients had received prior treatment. The authors reported that all patients reported an improvement in nasal breathing and in nasal appearance after one procedure and that three of the patients had some degree of scarring in the tip/supratip region after the first procedure (one of which was due to lack of adherence to postoperative instructions). The authors concluded that rhinophyma can be successfully treated with CO_2 laser in individuals with melanated skin, with careful and deep sculpting of the nose in cases with bulky disease. Limitations of the study include the retrospective single-center design; small sample size; and lack of a comparator group or treatment.

Noyman et al. (2025) evaluated the efficacy of treating severe rhinophyma with nonfractional ablative CO_2 laser in a single-center, retrospective cohort study. The study included 16 patients (15 males) with an average age at diagnosis of 67 years (range, 29-89 years); the average age at the time of treatment was 69 years (range, 43-90 years), and the average duration of symptoms was 7.8 years (range, 6 months to 20 years). Long-term results were assessed by telephonic contact, with the completion of a questionnaire that assessed satisfaction and recurrence. The authors reported that at the 3-month follow-up, nine patients had excellent aesthetic outcomes, four had very good aesthetic outcomes, two had good aesthetic outcomes, and one had moderate aesthetic outcomes. Two patients died due to reasons unrelated to the procedure or to rhinophyma, and one was lost to follow-up. Regarding pain post procedure, the authors reported that 10 patients experienced no or mild pain, two reported moderate pain, and one reported severe pain. Other adverse events that were reported by the authors included mild scarring in one patient and temporary swelling in another patient; no adverse events were reported to be long term. Regarding long-term outcomes, eight patients reported that the aesthetic treatment outcome was fully maintained, while two patients experienced minimal relapses, two had partial relapses, and one experienced a complete recurrence at 2.5 years following the procedure. Patient satisfaction following treatment was reportedly high, with an average satisfaction score of 7.9 out of 10, and 11 patients stated that they would recommend this treatment to someone with a similar problem. The authors concluded that nonfractional ablative CO_2 laser resurfacing proved to be safe, well tolerated, effective, and sustainable for the treatment of rhinophyma, with a high satisfaction rate. Limitations of the study include the small sample size, lack of a comparison group, single-center and retrospective design of the study, and lack of information regarding the race of the patients.

Zhai et al. (2024) conducted a systematic review and meta-analysis to synthesize and compare the clinical efficacy of IPL and PDL therapies for the management of rosacea. The meta-analysis included data from four studies with 141 adults. Three of the four studies were prospective split-face studies, and one was a retrospective study. The authors reported that the meta-analysis did not reveal a statistically significant difference between IPL and PDL in the rate of achieving greater than 50% clearance (100% in the PDL group and 88.89% in the IPL group); however, the authors reported that the IPL group had a significantly higher rate of clearance (77.78%), exceeding 75%, than the PDL group (66.67%). The authors also reported that the change in erythema index was similar between the two treatment modalities and that the PDL group reported a notably lower VAS pain score than the IPL group (reported in three of the four studies). The authors concluded that either PDL or IPL appears to be effective for the management of rosacea, with IPL exhibiting a slight advantage in achieving a higher rate of substantial clearance; PDL may be preferred by those with lower tolerance for posttreatment discomfort. The authors stated that the existing literature that compares these two therapies is limited and warrants further well-designed, large-scale studies to establish the optimal treatment for rosacea. Limitations include the small number of studies available for inclusion; small sample size; heterogeneity of the study designs; individualization of settings for PDL and IPL; and lack of information regarding long-term follow-up.

Martignago et al. (2024) conducted a systematic review to evaluate the efficacy and safety of IPL treatment for rosacea. The review included 14 studies (10 case series and four clinical trials), with 699 individuals (age range, 15-78 years) who had Fitzpatrick skin types I to IV. Studies were included if they were published in English and had no restrictions on publication date or status regardless of whether they included a control group. Three studies included only females, while the other 11 studies included both males and females. Study populations ranged from four to 260 individuals, and all studies used IPL alone as an intervention group, with four studies featuring a control group (three compared the treated

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group with PDL, and one used untreated individuals as controls). The authors reported that most studies demonstrated the positive effects of IPL treatment on telangiectasia and erythema in rosacea and that the positive effects of IPL persisted after treatment in all of the studies, as the area of telangiectasia and erythema, as well as the number of lesions, were significantly reduced after treatment. The authors also reported that adverse effects (pain, edema, minimal bruising, and burning sensations) were transitory. The authors concluded that while most of the included studies show the efficacy of IPL in the treatment of rosacea, the poor quality of the studies was of concern. Limitations of this systematic review include the poor methodological quality of the studies, heterogeneity of the treatment protocols and assessment tools used, and small study populations in the majority of the studies.

Piccolo et al. (2024) conducted a single-center prospective study to evaluate the efficacy of IPL therapy for the treatment of vascular lesions. The study included 39 adults (15 males; age range, 18-75 years) who were affected by telangiectasia (11 participants), rosacea (17 participants), erythrosis (nine participants), and poikiloderma (two participants). Each participant received IPL therapy in three treatment sessions that were spaced 1 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 5-point scale before each treatment, immediately after, and 3 days, 21 days, 45 days, and 3 months after the last treatment session. The authors reported that 21 participants (53.8%) achieved excellent improvement, 13 participants (33.3%) achieved good improvement, three participants (7.7%) achieved moderate improvement, and two participants (5.1%) achieved mild improvement. The authors concluded that the IPL system may represent successful treatment to improve vascular lesions that are resistant to laser therapy. The study is limited by the single-center design, small sample size, and short follow-up period.

Nguyen et al. (2024b) conducted a prospective, controlled, single-center study that compared the efficacy and safety of the variable-sequenced, large-spot, 532-nm KTP laser with those of the 595-nm PDL in treating rosacea. Enrolled were 45 adults (mean age, 51 ±11,6 years; 78.6% female) who had rosacea and were assigned in a 2:1 allocation to undergo either KTP laser (n = 30) or PDL therapy (n = 15). Each participant received up to three treatment sessions at intervals of 6 to 8 weeks, with a follow-up visit scheduled at 6 weeks post treatment. The primary end point was the improvement of rosacea-associated erythema at 6 weeks after the last treatment session compared with baseline. Three-dimensional photos were obtained at the beginning of each treatment session and at the 6-week posttreatment visit. The photos were assessed by two blinded independent, board-certified dermatologists for improvements using the Global Aesthetic Improvement Scale. The authors reported that participants who received KTP treatment reported a significant improvement in flushing and persistent erythema, while those in the PDL group also noted a reduction in persistent erythema but no significant difference in flushing. The authors also reported that the participants who received KTP rated their pain intensity significantly lower than those in the PDL group and that all participants in the KTP group experienced posttreatment mild to moderate swelling and erythema, with approximately 20% also having purpuric reactions that lasted for 1.3 ±2.7 days. In the PDL group, the authors reported that all participants reported swelling and purpura after treatment, which lasted for an average of 6.9 ±3.9 days; approximately 35% developed crusts, which lasted for 2.2 ±3.5 days. No reports of serious adverse effects were reported by the authors, and no participants in either treatment group discontinued the study due to adverse events. The authors concluded that both KTP laser and 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 PDL. However, secondary symptoms of rosacea, such as burning sensation, edema, and dry sensitivity, seemed to respond more favorably to PDL treatments, although KTP exhibited fewer posttreatment reactions. The study is 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 use of three different PDL systems.

Badawi et al. (2020) conducted a study to evaluate the efficacy and safety of fractional ablative 2,940-nm Er:YAG laser. The study included 16 participants, with a mean age of 57.8 years, who had mild to moderate rhinophyma for 2 to 15 years. Only one participant 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 the treatment of mild to moderate rhinophyma, with a rapid and pain-free recovery period. They concluded that further research is needed to confirm their findings and to optimize laser settings and the number of treatment sessions. They noted that the study is limited by the lack of histopathologic examination to rule out coexisting pathology and to demonstrate histopathologic improvement of the treated area.

Zhao et al. (2020) performed a retrospective study to investigate the efficacy of dye pulsed light (DPL) treatment for ETR and determine the factors affecting that efficacy. Overall, 65 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 posttreatment 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

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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 pretreatment erythema scores, skin type, pretreatment VISIA percentile ranking, sex, age, and lesion site ($p > 0.05$). Regarding telangiectasia, the treatment efficacy was greater in mild telangiectasia than in 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 individuals with ETR; 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 and the patient's Global Improvement Assessment and Global Flushing Severity Score, were not investigated. Also, the study was retrospective and nonrandomized. Further prospective research that includes RCTs is needed to validate these findings.

Seo et al. (2016) compared the effectiveness of the dual-wavelength long-pulsed 755-nm alexandrite/1,064-nm Nd:YAG laser (LPAN) with that of 585-nm PDL for rosacea in a randomized, single-blinded, comparative study. The erythema index was measured by spectrophotometer, and digital photographs were evaluated by consultant dermatologists for Physician Global Assessment. Subjective satisfaction surveys and adverse events were recorded. Overall, 49 participants with rosacea were enrolled in the study, and 12 dropped out. Full face received four consecutive monthly treatments with LPAN or PDL and was 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 Global Assessment, and participant-rated treatment satisfaction. PDL showed more adverse effects, including vesicles, than LPAN. No other serious or permanent adverse events were observed in both treatments. The authors concluded that both LPAN and PDL may be effective and safe treatments for rosacea. According to the authors, there are several limitations in the general application of the study findings. First, as with all studies that compare 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, the erythema index might not reflect the entire severity of rosacea or facial erythema. Third, in participants who were receiving LPAN treatments, it is difficult to determine the effect of each laser separately. Fourth, all participants were Korean and had darker skin types, which may limit the generalizability of the study. The authors stated 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.

Clinical Practice Guidelines

American Academy of Dermatology (AAD)

The AAD does not have clinical guidelines 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 IPL, KTP crystal laser, or PDL devices, can be used to effectively treat persistent central facial erythema without papulopustular lesions; this is based on their systematic review and meta-analysis of lower-quality clinical trials or studies that had limitations and inconsistent findings. The authors consider the benefit of device treatment for rosacea in that therapeutic effects are generally seen over a limited number of treatment sessions, which contrasts with the need for daily treatment over long periods of time with topical or oral medication. They note that once an end point 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 state that more data are needed on the optimal use of specific devices and topical α-agonist therapy in combination.

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

The consensus recommendations made by the AARS for the treatment of phymatous rosacea include a low recommendation for surgical therapy for fully developed phymatous changes, 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 (Del Rosso et al., 2020).

National Rosacea Society (NRS)

In the NRS's practical guidance that addresses rosacea, the NRS identifies monotherapies and multimodal treatment approaches for the clinical management of rosacea, including topical, systemic, laser and light, alternative, and combination therapies. The NRS states 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 IPL can be considered 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, 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., 2024a).

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 PDL and IPL therapies as established practice in removing telangiectasia and diminishing erythema; however, the NRS acknowledges the lack of quality clinical evidence to support these therapies and assigns a weak rating (Thiboutot et al., 2020).

U.S. Food and Drug Administration (FDA)

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

Phototherapy

Several hundred different phototherapy devices have been approved by the FDA through the 510(k) premarket approval process. These include devices that deliver blue, green, and yellow light phototherapy; photothermolysis devices; intense pulsed dye lasers; and near-infrared lasers. Refer to the following website for more information (use product codes FTC or GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 6, 2026)

Photodynamic Therapy

A number of different photodynamic therapy devices have been approved by the FDA through their premarket approval process. Refer to the following website for more information (use product code MVF): https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm. (Accessed June 6, 2026)

Pulsed Dye Laser

Pulsed dye lasers are classified as Class II devices. In 1986, the Candela Corporation manufactured the first pulsed dye laser that was approved by the FDA through the 510(k) premarket approval process for the treatment of cutaneous vascular lesions. Since then, various models have been developed and deemed substantially equivalent by the FDA. Refer to the following website for more information (use product code GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 8, 2026)

Laser Therapy

Several flashlamp-pumped pulsed dye lasers, xenon-chloride excimer lasers, neodymium:yttrium-aluminum garnet (Nd:YAG), and erbium:yttrium-aluminum garnet (Er:YAG) lasers have received FDA approval. Refer to the following website for more information (use product code GEX): http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm. (Accessed June 6, 2026)

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Policy History/Revision Information

Date	Summary of Changes
11/01/2026	**Supporting Information** • Updated *Clinical Evidence* and *References* sections to reflect the most current information • Archived previous policy version 2026T0337GG

Instructions for Use

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

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