

Policy # 00162 Original Effective Date: 03/07/2005 Current Effective Date: 11/25/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

Note: Light Therapy for Psoriasis is addressed separately in medical policy 00131.

## When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- Benefits are available in the member's contract/certificate, and
- Medical necessity criteria and guidelines are met.

Based on review of available data, the Company may consider vascular lesions to be **eligible for coverage.**\*\*

#### Patient Selection Criteria

Coverage eligibility for laser destruction of cutaneous vascular\* lesions will be considered when any of the following are present:

- Congenital port-wine stains; **OR**
- Cutaneous hemangioma/hemangiomata (e.g., venous, arteriovenous, lymphatic).

#### Note:

\* Hypertrophic burn scars, viral or plantar warts, and any other non-vascular skin lesion are not considered to be vascular proliferative lesions. Therefore, laser therapy for these conditions should not be reported with CPT codes 17106, 17107, or 17108.

## **Services Are Considered Investigational**

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers laser treatment of active acne to be **investigational.**\*

Based on review of available data, the Company considers laser treatment of rosacea to be investigational.\*

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**Note:** The use of laser therapy, intense pulsed light therapy, electrosurgery, cryosurgery, and chemosurgery (i.e., epidermal/dermal chemical peels) for the treatment of acne scarring or effects associated with rosacea (e.g. erythema, telangiectasia, scarring) is not covered by the Company because it is considered a cosmetic service.

# **Policy Guidelines**

Request for laser treatment of vascular lesions may require detailed medical documentation, including:

- History of medical condition requiring treatment including specific location and size of the lesion, recurrent or persistent functional impairment caused by the abnormality
- Treatments tried, failed, contraindicated or on-going, including dates, duration, and reason for discontinuation
- High-quality color photograph(s)
- Physician plan of care with proposed procedures and whether this request is part of a staged procedure.

# **Background/Overview**

## Acne

Acne is a very common disorder of the pilosebaceous follicles that primarily affects adolescents and young adults and may be classified as inflammatory or noninflammatory. Acne is characterized by comedones, nodules and eruptions of papules, pustules and nodulocystic lesions. Lesions are found in areas with the greatest concentration of sebaceous glands, i.e., the face, neck and upper part of the trunk. The four causal factors of acne are androgen-mediated sebaceous gland hyperplasia and excess sebum production; abnormal follicular keratinization, which results in plugging of the follicles, and comedo formation; proliferation of propionibacterium acnes (*P. acnes*) and inflammation resulting from the chemoattractant and proinflammatory byproducts of *P. acnes*. Genetic factors, diet and stress may also contribute to the development and severity of acne. Treatment of active acne usually consists of good skin care regimen, benzoyl peroxide, antibiotics and retinoids. Active acne is distinct from acne scarring, which may occur from tissue damage after inflammatory lesions subside.

Pulsed dye laser has been used in the treatment of acne scarring; however, more recently, lasers have been investigated for the treatment of active inflammatory acne. Laser therapy at various irradiation levels or fluences (e.g., low- and mid-level irradiation lasers and long-pulse diode lasers) has been used to destroy active acne lesions and enlarged sebaceous glands. Lasers are believed to improve active acne lesions by reducing the presence of *P. acnes*, which contain porphyrins that are destroyed by exposure to light of specific wavelengths (i.e., blue light of 405–420 nm). Lasers may also have anti-inflammatory effects (i.e., red light of 660 nm) that may improve active acne treatment to limit tissue damage and potential treatment-related scarring. Laser treatment of active acne lesions may also reduce potential acne scarring that can occur in severe cases.

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#### Rosacea

Rosacea is characterized by episodic erythema, edema, papules, and pustules that occur primarily on the face but may also be present on the scalp, ears, neck, chest, and back. On occasion, rosacea may affect the eyes. Patients with rosacea tend to flush or blush easily. Because rosacea causes facial swelling and redness, it is easily confused with other skin conditions, such as acne, skin allergy, and sunburn.

Rosacea mostly affects adults with fair skin between the ages of 20 and 60 years and is more common in women, but often most severe in men. Rosacea is not life-threatening, but if not treated, it may lead to persistent erythema, telangiectasias, and rhinophyma (hyperplasia and nodular swelling and congestion of the skin of the nose). The etiology and pathogenesis of rosacea are unknown but may result from both genetic and environmental factors. Some theories on the causes of rosacea include blood vessel disorders, chronic *Helicobacter pylori* infection, Demodex folliculorum (mites), and immune system disorders.

While the clinical manifestations of rosacea do not usually impact the physical health status of the patient, psychological consequences from the most visually apparent symptoms (ie, erythema, papules, pustules, telangiectasias) may impact quality of life. Rhinophyma, an end-stage of chronic acne, has been associated with obstruction of nasal passages and basal cell carcinoma in rare, severe cases. The probability of developing nasal obstruction or basal or squamous cell carcinoma with rosacea is not sufficient to warrant the preventive removal of rhinophymatous tissue.

#### Treatment

Rosacea treatment can be effective in relieving signs and symptoms. Treatment may include oral and topical antibiotics, isotretinoin, b-blockers, alpha<sub>2</sub>-adrenergic agonists (e.g., oxymetazoline, clonidine), and anti-inflammatories. Patients are also instructed on various self-care measures such as avoiding skin irritants and dietary items thought to exacerbate acute flare-ups.

Nonpharmacologic therapy has also been tried in patients who cannot tolerate or do not want to use pharmacologic treatments. To reduce visible blood vessels, treat rhinophyma, reduce redness, and improve appearance, various techniques have been used such as laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery. Various lasers used include low-powered electrical devices and vascular light lasers to remove telangiectasias, carbon dioxide lasers to remove unwanted tissue from rhinophyma and reshape the nose, and intense pulsed lights that generate multiple wavelengths to treat a broader spectrum of tissue.

#### **Port wine stains**

Port wine stains are the most common of the vascular malformations, affecting approximately 3 in 1000 children. They are composed of networks of ectatic vessels and primarily involve the papillary dermis. Unlike many other birthmarks, port wine stains do not resolve spontaneously. In contrast, they typically begin as pink macules and become redder and thicker over time due to decreased sympathetic innervation. The depth of the skin lesions ranges from about 1 to 5 mm. Port wine stains are generally located on the face and neck but can occur in other locations such as the trunk or limbs.



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Before the availability of laser treatment in the 1980s, there were no effective therapies for port wine stains. A laser is a highly focused beam of light that is converted to heat when absorbed by pigmented skin lesions. Several types of lasers have been used to treat port wine stains. Currently, the most common in clinical practice is the PDL, which uses yellow light wavelengths (585-600 nm) that selectively target both oxyhemoglobin and deoxyhemoglobin. PDLs penetrate up to 2 mm in the skin. Newborns and young children, who have thinner skin, tend to respond well to this type of laser; the response in thicker and darker lesions may be lower. Other types of lasers with greater tissue penetration and weaker hemoglobin absorption are used for hypertrophic and resistant port wine stains. In particular, alternatives to the PDL are the long-pulsed 1064 nm Nd:YAG and 755 nm pulsed Alexandrite lasers. The 1064 nm Nd:YAG laser requires a substantial degree of skill to use to avoid scarring. Carbon dioxide and argon lasers are relatively nonselective; they were some of the first lasers used to treat port wine stains but were associated with an increased incidence of scarring and are not currently used frequently in clinical practice to treat port wine stains. IPL devices emit polychromatic high-intensity pulsed light. Pulse duration is in the millisecond range, and devices use an emission spectrum ranging from 500 to 1400 nm. Compared with other types of lasers, IPL devices include both the oxyhemoglobin selective wavelengths emitted by PDL systems and longer wavelengths that allow deeper penetration into the dermis.

## FDA or Other Governmental Regulatory Approval

## U.S. Food and Drug Administration (FDA)

#### Acne

A number of laser and focused light devices have received marketing clearance for the treatment of acne via the FDA's 510(k) mechanism. These include lasers that emit light at 1320nm (Candela Smoothbeam<sup>TM‡</sup> and CoolTouch<sup>®</sup>)<sup>‡</sup>; intense pulsed light systems, which emit light in the range of 590 to 1200nm (Radiancy ClearTouch<sup>TM‡</sup>, MED flash II and Ellispse I<sup>2</sup>PL)<sup>‡</sup>; pulsed dye lasers (ICN Photonics NLite System); and lasers or high-intensity light devices, which emit violet or blue (around 414nm) and red (around 633nm) light (Aura<sup>TM</sup>, Clearlight and Dermillume)<sup>‡</sup>. The specific indications for these devices vary; Candela Smoothbeam is indicated solely for the treatment of acne on the back, others are indicated for the treatment of inflammatory acne or for mild to moderate acne with no location specified. In 2006, a thermal device (ThermaClear<sup>TM</sup>)<sup>‡</sup> was cleared for marketing for the "treatment of individual acne pimples in persons with mild to moderate inflammatory acne" in both a practitioner's office environment and a consumer home-use environment.

### Rosacea

Several laser and light therapy systems have been cleared for marketing by the U.S. Food and Drug Administration through the 510(k) process for various dermatologic indications, including rosacea. For example, rosacea is among the indications for:

- Vbeam laser system (Candela)
- Stellar M22<sup>™</sup><sup>+</sup> laser system (Lumenis)
- excel  $VT^{\mathbb{R}^{\ddagger}}$ , excel  $V^{\mathbb{R}^{\ddagger}}$ , and  $xeo^{\mathbb{R}^{\ddagger}}$  laser systems (Cutera)
- Harmony<sup>®‡</sup> XL multi-application platform laser device (Alma Lasers, Israel)
- UV-300 Pulsed Light Therapy System (New Star Lasers)
- CoolTouch<sup>®‡</sup> PRIMA Pulsed Light Therapy System (New Star Lasers).

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FDA product code: GEX.

#### **Port wine stains**

Several laser systems have been cleared for marketing by the U.S. Food and Drug Administration (FDA) through the 510(k) process for a variety of dermatologic indications, including treatment ofport wine stains.

Approved lasers for this indication include the Candela<sup>®‡</sup> PDL system (Candela Corp., Wayland,MA), the Cynosure Photogenica<sup>®‡</sup> PDL (Cynosure Inc., Westford, MA), and the CynosureNd:YAG laser system. In addition, the Cynergy<sup>™‡</sup> Multiplex Laser (Cynosure), a combinedNd:YAG and PDL was approved by FDA in 2005 for treatment of benign vascular and vasculardependent lesions, including port wine stains.

In 2003, the Lumenis<sup>®‡</sup> family of IPL systems was approved by FDA; indications for use includedermatologic applications. Subsequently, the NannoLight<sup>®‡</sup> IPL system (Global USA Distribution)was approved by FDA in 2008 and the Mediflash3 and Esterflash3 systems (Dermeo) wereapproved in 2010 for indications specifically including treatment of port wine stains.

## **Rationale/Source**

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

### Acne

Two systematic reviews of light therapies for treatment of active acne were identified. Both reviews included studies on photodynamic therapy, as well as light and laser therapy. Neither review conducted any pooled analyses of laser treatment studies due to heterogeneity between studies (e.g. different wavelengths of light were used). The two systematic reviews had similar assessments of the literature. Hamilton and colleagues identified 10 randomized controlled trials (RCTs) comparing light therapy to placebo and 3 RCTs comparing light therapy to topical treatment of acne. The authors commented that studies of light therapy tended to be small (all had fewer than 50 participants), of short duration and of variable quality, and that a few compared light therapy to conventional treatment. They concluded: "our review found only limited or no benefit is given by light therapies alone...Further trials comparing light therapy with usual treatment, using a larger effect size in the power calculations, would be helpful to determine the usefulness of light therapy in treating acne." The other systematic review by Haedersdal and colleagues included 11 RCTs on light treatments (other than photodynamic therapy) and stated that that most of the studies had suboptimal methods. For example, few studies described their randomization method and most had large losses to follow-up without intention to treat analysis. The authors state, "Based on the present best available evidence, we conclude that optical treatments with lasers, light sources and PDT possess the potential to improve inflammatory acne on a short-term basis with the most consistent

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outcomes for PDT. We recommend that patients are informed of the existing evidence, which denotes that optical treatments for acne today are not included among first-line treatments" There is no separate conclusion focusing on laser therapy. The systematic reviews identified a number of side effects from optical treatments, and these include pain, erythema, edema, crusting, hyperpigmentation, and pustular eruptions.

Key individual RCTs with at least 40 participants are described as follows:

Seaton et al., 2003: This trial was a double-blind RCT of 41 adults with mild to moderate facial inflammatory acne (i.e., Leeds acne severity score of between 2 and 7). Patients were randomized to receive a single low fluence pulsed dye laser treatment or sham treatment. At 12 weeks, Leeds acne scores fell from 3.8 to 1.9 in the treatment group and from 3.6 to 3.5 in the control group. Total lesion counts fell by 53% and 9% and inflammatory lesion counts fell by 49% and 10% in the laser treatment group and control group, respectively. While the authors reported statistically significant improvements, they concluded that "laser treatment should be further explored as an adjuvant or alternative to daily conventional pharmacological treatments."

Orringer et al., 2004: The article reported on a single-blind, split-face RCT of 40 patients (aged 13 years or older with a Leeds acne score of two or greater) who were randomized to receive either one or two sessions of pulsed dye laser treatment (3 J/cm2 fluence) to half of the face with the opposite, non-treated side serving as the control. At 12 weeks, changes in lesion counts (including pustules, comedones, macules, cysts, and papules) and mean Leeds acne scores were not significantly different for the treated versus untreated sides of the face. The authors concluded that "…additional well designed studies are needed before the use of pulse dye laser becomes a part of acne therapy."

Orringer et al., 2007: This RCT assessed the efficacy of a 1320-nm laser (CoolTouch II) in 46 patients in a split-face design. Laser treatment was given once every three weeks, with blinded evaluation by a panel of three dermatologists (from photographs taken at 7 and 14 weeks). Thirty patients completed the 14-week assessment (35% dropout); data were carried forward to adjust for subjects who may have dropped out of the study due to lack of effect. The authors report that the treated side remained unchanged at 0.22 cysts (10 total cysts in 46 subjects) while the untreated side increased from 0.27 to 0.70 cysts. Subjective patient reports (of 37 who completed at least the 7-week assessment; not blinded to treatment) favored the treated side over the control side for a decrease in acne (59%) and oily skin (54%). No differences were found between the treated and un-treated sides in the number of papules, pustules, open comedones, or closed comedones at 14 weeks.

Laheta, 2009: This study included 45 patients with mild to moderate acne who were randomly assigned to one of three groups (15 patients per group). Group A received pulsed dye laser therapy (3 J/cm2 fluence) every two weeks for six sessions; Group B applied topical treatment with 0.1% tretinoin cream every evening and 5% benzoyl peroxide gel every morning; and Group C underwent chemical peeling using trichloroacetic acid 25%. An assessor blinded to treatment group evaluated outcomes; 41 patients were included in the analysis. There was no significant



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difference between groups in the acne severity score (0=no acne to 10=severe acne) at the end of the 3-month treatment period. Mean scores were  $0.56 \pm 0.57$  for Group A,  $0.65 \pm 0.47$  for Group B, and  $0.68 \pm 0.50$  for Group C (p=0.38). The analysis of disease severity did not adjust for baseline scores, and standard deviations were large due to the small number of participants in each group. The degree of clinical response (marked or moderate) and side effects (trace, mild, or moderate) also did not differ significantly between the three groups. The proportion of patients with moderate side effects was 23% in Group A, 15% in Group B, and 13% in Group C (overall p-value=0.95).

#### Summary

Due to the small sample sizes of the published trials, lack of long-term follow-up, small number of studies on any particular type of laser, and paucity of studies comparing light therapy to standard acne treatments, the evidence is insufficient to draw conclusions about the impact of laser treatments on health outcomes in patients with active acne. Therefore, the technology is considered investigational.

#### Rosacea

Rosacea is a chronic, inflammatory skin condition without a known cure; the goal of treatment is symptom management. Nonpharmacologic treatments, including laser and light therapy as well as dermabrasion, which are the focus of this evidence review, are proposed for patients who do not want to use or are unresponsive to pharmacologic therapy.

#### **Summary of Evidence**

For individuals who have rosacea who receive nonpharmacologic treatment (e.g., laser therapy, light therapy, dermabrasion), the evidence includes systematic reviews and several small, randomized, split-face design trials. Relevant outcomes are symptoms, change in disease status, and treatmentrelated morbidity. The systematic reviews reported favorable effects on erythema and telangiectasia with several laser types, including intense pulsed light (IPL), pulsed dye lasers, and neodymiumdoped yttrium aluminum garnet (Nd:YAG) lasers. However, the systematic reviews did not pool results from individual studies and the studies differed in the specific lasers being compared. Overall, the systematic review results were insufficient to establish whether any laser type is more effective and safe than others. The randomized controlled trials (RCTs) evaluated laser and light therapy. One RCT compared combination laser and pharmacologic therapy with pharmacologic therapy alone and 2 RCTs compared combination laser and pharmacologic therapy with laser therapy alone, but the lack of an arm evaluating laser therapy alone against established pharmacologic therapy does not allow a direct assessment on the efficacy of laser or light treatment compared with alternative treatments. No trials assessing other nonpharmacologic treatments were identified. There is a need for RCTs that compare nonpharmacologic treatments with placebo controls and with pharmacologic treatments. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

### Port Wine Stains Summary of Evidence

Studies have generally found that laser treatment can be effective at lightening port wine stains. The preponderance of evidence is on the pulsed dye laser; there is insufficient evidence from comparative

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studies that 1 type of laser results in more lightening than another. There is insufficient evidence that adding topical angiogenesis inhibitor to laser therapy results in better outcomes than lasers alone. There was 1 positive RCT and 1 negative RCT. No comparative studies were identified on lasers combined with any other treatments. Thus, laser treatment may be considered medically necessary in certain situations for patients with port wine stains.

# **Supplemental Information**

## Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in 'Supplemental Information' if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

### American Acne and Rosacea Society

In 2014, the American Acne and Rosacea Society issued consensus recommendations on the management of rosacea. The Society stated that lasers and intense pulsed light (IPL) devices could improve certain clinical manifestations of rosacea that have not responded to medical therapy. The recommendations indicated that these therapies would have to be repeated intermittently to sustain improvement.

In 2016, the American Acne and Rosacea Society issued updated consensus recommendations on the management of rosacea. The update focused on how medical and device therapies are used--whether concurrently or in a staggered fashion--noting that there is a lack of evidence to justify either use. The Society's consensus recommendation on rosacea management correlated with clinical manifestations observed at the time of presentation is summarized in Table 1:

| unugement of Robuccu  |  |                    |
|---|--|--------------------|
| Condition   | Recommendation   | Grade <sup>a</sup> |
| Persistent central facial<br>erythema without<br>papulopustular lesions | IPL, potassium titanyl phosphate crystal laser, or pulsed dye laser  | В                  |
| Diffuse central facial<br>erythema with<br>papulopustular lesions       | "While the data on the use of IPL, potassium titanyl<br>phosphate or pulsed dye laser are limited for papulopustular<br>lesions, these options are useful to treat erythema" | NR                 |
| Granulomatous rosacea   | <ul> <li>Intense pulsed dye laser</li> <li>"No current standard of treatment; limited data based on case reports"</li> </ul>   | С                  |

 Table 1. Recommendations on Use of Lasers and Intense Pulsed Light Devices for the Management of Rosacea



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| Phymatous Rosacea | <ul> <li>"Surgical therapy for fully developed phymatous changed (carbon dioxide laser, erbium-doped [YAG] laser, electrosurgery, dermabrasion)"</li> <li>"Treatment selection dependent on stage of development (early or fibrotic) and extent of inflammation (active or burnt out)"</li> </ul> | С |
|-------------------|---|---|
|                   |   |   |

IPL: intense pulsed light, YAG: yttrium aluminum garnet; NR: not reported. <sup>a</sup> Grade A: Criteria not described in recommendation; Grade B: Systematic review/meta-analysis of lower-quality clinical trials or studies with limitations and inconsistent findings; lower-quality clinical trial; Grade C: Consensus guidelines; usual practice, expert opinion, case series—limited trial data.

### **Rosacea Consensus Panel**

In 2017, the Rosacea Consensus panel, comprised of international experts including representatives from the U.S., published recommendations for rosacea treatment. The panel agreed that treatments should be based on phenotype. IPL and pulsed dye laser were recommended for persistent erythema, but not for transient erythema. IPL and lasers were also recommended for telangiectasia rosacea.

The panel updated their recommendations on rosacea treatment in 2019, agreeing that lasers were recommended for persistent centrofacial erythema. They also noted that "use of IPL and vascular lasers in darker skin phototypes requires consideration by a healthcare provider with experience..., as it can result in dyspigmentation." The panel also acknowledged that combining treatments could benefit patients with more severe rosacea and multiple rosacea features; however "there remains an ongoing need for more studies to support combination treatment use in rosacea."

#### National Rosacea Society

In 2019, the National Rosacea Society Executive Committee published an expert consensus document on management options for rosacea. This document endorses treatment goals of an Investigator Global Assessment score of 0 and normalization of skin tone and color due to the notable impact of rosacea on patient quality of life. Light devices are discussed as treatment options along with medications, skin care, and lifestyle interventions. Based on weak evidence, IPL, pulsed dye lasers, and potassium titanyl phosphate lasers are listed as moderately effective treatment options for persistent erythema, particularly due to telangiectasia. Both IPL and potassium titanyl phosphate are described as having at least some efficacy for flushing. Nonpharmacologic interventions that are listed as more highly effective treatment options for non-inflamed phymas (based on weak evidence) include carbon dioxide lasers, erbium lasers, cold steel, electrosurgery, and radiofrequency; these same interventions are listed for use in combination with other treatment modalities for inflammatory phymas. Carbon dioxide lasers, erbium lasers, cold steel, electrosurgery, and radiofrequency carry a risk of post-inflammatory hyperpigmentation and should only be provided by appropriately trained individuals.

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## **U.S. Preventive Services Task Force Recommendations**

Not applicable.

## **Medicare National Coverage**

There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

## **Ongoing and Unpublished Clinical Trials**

Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

| NCT No.     | Trial Name  | Planned<br>Enrollment | Completion<br>Date |
|-------------|---|-----------------------|--------------------|
| Ongoing     |   |                       |                    |
| NCT04889703 | A Pilot Study Testing the Effects of Chemical<br>Peels in Patients With Rosacea | 20                    | May 2024           |
| NCT05592548 | Rosacea Treatment Using Non-thermal (Cold)<br>Atmospheric Plasma Device         | 10                    | Jun 2024           |

#### **Table 2. Summary of Key Trials**

NCT: national clinical trial.

# **References**

- 1. Hamilton FL, Car J, Lyons C et al. Laser and other light therapies for the treatment of acne vulgaris: systematic review. Br J Dermatol 2009; 160: 1273-1285.
- 2. Haedersdal M, Togsverd-Bo K, Wiegell SR et al. Long-pulsed dye laser versus long-pulsed dye laser-assisted photodynamic therapy for acne vulgaris: a randomized controlled trial. J Am Acad Dermatol 2008; 58(3):387-94.
- 3. Seaton ED, Charakida A, Mouser PE et al. Pulsed-dye laser treatment for inflammatory acne vulgaris: randomized controlled trial. Lancet 2003; 362(9393):1347-52.
- 4. Orringer JS, Kang S, Hamilton T et al. Treatment of acne vulgaris with a pulsed dye laser: a randomized controlled trial. JAMA 2004; 291(23):2834-9.
- Orringer JS, Kang S, Maier L et al. A randomized, controlled, split-face clinical trial of 1320-nm Nd:YAG laser therapy in the treatment of acne vulgaris. J Am Acad Dermatol 2007; 56(3):432-8.
- 6. Laheta TM. Role of the 585-nm pulsed dye laser in the treatment of acne in comparison with other topical therapeutic modalities. J Cesmetic Laser Ther 2009; 11: 118-124.
- 7. http://www.skincarephysicians.com/acnenet/PhysicalProcedures.html .
- 8 Husein-ElAhmed H, Steinhoff M. Light-based therapies in the management of rosacea: a systematic review with meta-analysis. Int J Dermatol. Jun 05 2021. PMID 34089264
- 9. van Zuuren EJ, Fedorowicz Z, Carter B, et al. Interventions for rosacea. Cochrane Database Syst Rev. Apr 28 2015; (4): CD003262. PMID 25919144



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- van Zuuren EJ, Fedorowicz Z, Tan J, et al. Interventions for rosacea based on the phenotype approach: an updated systematic review including GRADE assessments. Br J Dermatol. Jul 2019; 181(1): 65-79. PMID 30585305
- 11. Wat H, Wu DC, Rao J, et al. Application of intense pulsed light in the treatment of dermatologic disease: a systematic review. Dermatol Surg. Apr 2014; 40(4): 359-77. PMID 24495252
- 12. West TB, Alster TS. Comparison of the long-pulse dye (590-595 nm) and KTP (532 nm) lasers in the treatment of facial and leg telangiectasias. Dermatol Surg. Feb 1998; 24(2): 221-6. PMID 9491116
- Mark KA, Sparacio RM, Voigt A, et al. Objective and quantitative improvement of rosaceaassociated erythema after intense pulsed light treatment. Dermatol Surg. Jun 2003; 29(6): 600-4. PMID 12786702
- 14. Taub AF. Treatment of rosacea with intense pulsed light. J Drugs Dermatol. Jun 2003; 2(3): 254-9. PMID 12848109
- 15. Schroeter CA, Haaf-von Below S, Neumann HA. Effective treatment of rosacea using intense pulsed light systems. Dermatol Surg. Oct 2005; 31(10): 1285-9. PMID 16188180
- 16. Karsai S, Roos S, Raulin C. Treatment of facial telangiectasia using a dual-wavelength laser system (595 and 1,064 nm): a randomized controlled trial with blinded response evaluation. Dermatol Surg. May 2008; 34(5): 702-8. PMID 18318728
- Papageorgiou P, Clayton W, Norwood S, et al. Treatment of rosacea with intense pulsed light: significant improvement and long-lasting results. Br J Dermatol. Sep 2008; 159(3): 628-32. PMID 18565174
- Neuhaus IM, Zane LT, Tope WD. Comparative efficacy of nonpurpuragenic pulsed dye laser and intense pulsed light for erythematotelangiectatic rosacea. Dermatol Surg. Jun 2009; 35(6): 920-8. PMID 19397667
- 19. Lane JE, Khachemoune A. Use of intense pulsed light to treat refractory granulomatous rosacea. Dermatol Surg. Apr 2010; 36(4): 571-3. PMID 20402938
- 20. Nymann P, Hedelund L, Haedersdal M. Long-pulsed dye laser vs. intense pulsed light for the treatment of facial telangiectasias: a randomized controlled trial. J Eur Acad Dermatol Venereol. Feb 2010; 24(2): 143-6. PMID 20205349
- 21. Fabi S, Peterson J, Goldman M. Combination 15% azelaic acid gel and intense pulse light therapy for mild to moderate rosacea. Lasers Surg Med 2011;43:9689.
- 22. Kassir R, Kolluru A, Kassir M. Intense pulsed light for the treatment of rosacea and telangiectasias. J Cosmet Laser Ther. Oct 2011; 13(5): 216-22. PMID 21848421
- 23. Kim TG, Roh HJ, Cho SB, et al. Enhancing effect of pretreatment with topical niacin in the treatment of rosacea-associated erythema by 585-nm pulsed dye laser in Koreans: a randomized, prospective, split-face trial. Br J Dermatol. Mar 2011; 164(3): 573-9. PMID 21143465
- 24. Huang YE, Li XL, Li TJ. [Clinical research of topical tacrolimus ointment combined with 585 nm pulsed dye laser in the treatment of rosacea]. J Clinical Dermatol 2012; 41:3089.
- 25. Tanghetti EA. Split-face randomized treatment of facial telangiectasia comparing pulsed dye laser and an intense pulsed light handpiece. Lasers Surg Med. Feb 2012; 44(2): 97-102. PMID 22180317
- 26. Alam M, Voravutinon N, Warycha M, et al. Comparative effectiveness of nonpurpuragenic 595nm pulsed dye laser and microsecond 1064-nm neodymium:yttrium-aluminum-garnet laser for



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treatment of diffuse facial erythema: A double-blind randomized controlled trial. J Am Acad Dermatol. Sep 2013; 69(3): 438-43. PMID 23688651

- 27. Friedmann DP, Fabi SG, Goldman MP, Guiha I. The effect of multiple sequential light sources to activate aminolevulinic acid in the treatment of acne vulgaris. Lasers Surg Med 2013;45:57.
- 28. Salem SA, Abdel Fattah NS, Tantawy SM, et al. Neodymium-yttrium aluminum garnet laser versus pulsed dye laser in erythemato-telangiectatic rosacea: comparison of clinical efficacy and effect on cutaneous substance (P) expression. J Cosmet Dermatol. Sep 2013; 12(3): 187-94. PMID 23992160
- 29. Seo HM, Kim JI, Kim HS, et al. Prospective Comparison of Dual Wavelength Long-Pulsed 755nm Alexandrite/1,064-nm Neodymium:Yttrium-Aluminum-Garnet Laser versus 585-nm Pulsed Dye Laser Treatment for Rosacea. Ann Dermatol. Oct 2016; 28(5): 607-614. PMID 27746641
- Handler MZ, Bloom BS, Goldberg DJ. IPL vs PDL in treatment of facial erythema: A split-face study. J Cosmet Dermatol. Dec 2017; 16(4): 450-453. PMID 28752575
- 31. Kim SJ, Lee Y, Seo YJ, et al. Comparative Efficacy of Radiofrequency and Pulsed Dye Laser in the Treatment of Rosacea. Dermatol Surg. Feb 2017; 43(2): 204-209. PMID 27893539
- 32. Kwon WJ, Park BW, Cho EB, et al. Comparison of efficacy between long-pulsed Nd:YAG laser and pulsed dye laser to treat rosacea-associated nasal telangiectasia. J Cosmet Laser Ther. Oct 2018; 20(5): 260-264. PMID 29388843
- 33. Campos MA, Sousa AC, Varela P, et al. Comparative effectiveness of purpuragenic 595 nm pulsed dye laser versus sequential emission of 595 nm pulsed dye laser and 1,064 nm Nd:YAG laser: a double-blind randomized controlled study. Acta Dermatovenerol Alp Pannonica Adriat. Mar 2019; 28(1): 1-5. PMID 30901061
- 34. Kim BY, Moon HR, Ryu HJ. Comparative efficacy of short-pulsed intense pulsed light and pulsed dye laser to treat rosacea. J Cosmet Laser Ther. Aug 2019; 21(5): 291-296. PMID 30285506
- 35. Maxwell EL, Ellis DA, Manis H. Acne rosacea: effectiveness of 532 nm laser on the cosmetic appearance of the skin. J Otolaryngol Head Neck Surg. Jun 2010; 39(3): 292-6. PMID 20470675
- 36. Tirico MCCP, Jensen D, Green C, et al. Short pulse intense pulsed light versus pulsed dye laser for the treatment of facial redness. J Cosmet Laser Ther. Feb 17 2020; 22(2): 60-64. PMID 32041440
- 37. Sodha P, Suggs A, Munavalli GS, et al. A Randomized Controlled Pilot Study: Combined 595nm Pulsed Dye Laser Treatment and Oxymetazoline Hydrochloride Topical Cream Superior to Oxymetazoline Hydrochloride Cream for Erythematotelangiectatic Rosacea. Lasers Surg Med. Jul 07 2021. PMID 34233378
- 38. Tanghetti E, Del Rosso JQ, Thiboutot D, et al. Consensus recommendations from the American acne rosacea society on the management of rosacea, part 4: a status report on physical modalities and devices. Cutis. Feb 2014; 93(2): 71-6. PMID 24605343
- 39. Del Rosso JQ, Tanghetti E, Webster G, et al. Update on the Management of Rosacea from the American Acne Rosacea Society (AARS). J Clin Aesthet Dermatol. Jun 2019; 12(6): 17-24. PMID 31360284
- 40. Schaller M, Almeida LM, Bewley A, et al. Rosacea treatment update: recommendations from the global Rosacea Consensus (ROSCO) panel. Br J Dermatol. Feb 2017; 176(2): 465-471. PMID 27861741

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- 41. Schaller M, Almeida LMC, Bewley A, et al. Recommendations for rosacea diagnosis, classification and management: update from the global Rosacea Consensus 2019 panel. Br J Dermatol. May 2020; 182(5): 1269-1276. PMID 31392722
- 42. Thiboutot D, Anderson R, Cook-Bolden F, et al. Standard management options for rosacea: The 2019 update by the National Rosacea Society Expert Committee. J Am Acad Dermatol. Jun 2020; 82(6): 1501-1510. PMID 32035944

## **Policy History**

| Original Effectiv | ve Date: 03/07/2005   |  |  |
|-------------------|---|--|--|
| Current Effectiv  | e Date: 11/25/2024  |  |  |
| 12/07/2004        | Medical Director review   |  |  |
| 12/14/2005        | Medical Policy Committee review   |  |  |
| 03/07/2005        | Managed Care Advisory Council approval  |  |  |
| 09/07/2005        | Medical Director review   |  |  |
| 09/20/2005        | Medical Policy Committee review. Laser treatment for scar revision removed from |  |  |
|                   | policy.   |  |  |
| 09/22/2005        | Quality Care Advisory Council approval  |  |  |
| 07/07/2006        | Medical Policy Committee approval. Format revision, including addition of FDA   |  |  |
|                   | and/or other governmental regulatory approval and rationale/source. Coverage    |  |  |
|                   | eligibility unchanged.  |  |  |
| 07/10/2007        | Medical Director review   |  |  |
| 07/18/2007        | Medical Policy Committee approval. No change to coverage eligibility.           |  |  |
| 07/02/2009        | Medical Director review   |  |  |
| 07/22/2009        | Medical Policy Committee approval. No change to coverage eligibility.           |  |  |
| 07/01/2010        | Medical Policy Committee Director approval.                                     |  |  |
| 07/21/2010        | Medical Policy Implementation Committee approval. No change to coverage.        |  |  |
| 07/07/2011        | Medical Policy Committee Director approval.                                     |  |  |
| 07/20/2011        | Medical Policy Implementation Committee approval. No change to coverage.        |  |  |
| 10/12/2011        | Coding correction.  |  |  |
| 06/28/2012        | Medical Policy Committee Director approval.                                     |  |  |
| 07/27/2012        | Medical Policy Implementation Committee approval. No change to coverage.        |  |  |
| 06/27/2013        | Medical Policy Committee Director approval.                                     |  |  |
| 07/17/2013        | Medical Policy Implementation Committee approval. No change to coverage.        |  |  |
| 07/10/2014        | Medical Policy Committee Director approval.                                     |  |  |
| 07/16/2014        | Medical Policy Implementation Committee approval. No change to coverage.        |  |  |
| 08/03/2015        | Coding update: ICD10 Diagnosis code section added; ICD9 Procedure code section  |  |  |
|                   | removed.  |  |  |
| 09/03/2015        | Medical Policy Committee Director approval.                                     |  |  |
| 09/23/2015        | Medical Policy Implementation Committee approval. No change to coverage.        |  |  |
| 09/08/2016        | Medical Policy Committee Director approval.                                     |  |  |
| 09/21/2016        | Medical Policy Implementation Committee approval. No change to coverage.        |  |  |
| 01/01/2017        | Coding update: Removing ICD-9 Diagnosis Codes                                   |  |  |
| 09/07/2017        | Medical Policy Committee Director approval.                                     |  |  |



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- 09/20/2017 Medical Policy Implementation Committee approval. No change to coverage.
- 09/06/2018 Medical Policy Committee Director approval.
- 09/19/2018 Medical Policy Implementation Committee approval. No change to coverage.
- 09/05/2019 Medical Policy Committee Director approval.
- 09/11/2019 Medical Policy Implementation Committee approval. No change to coverage.
- 09/03/2020 Medical Policy Committee Director approval.
- 09/09/2020 Medical Policy Implementation Committee approval. No change to coverage.
- 09/02/2021 Medical Policy Committee Director approval.
- 09/08/2021 Medical Policy Implementation Committee approval. No change to coverage.
- 02/09/2022 Coding Update
- 09/01/2022 Medical Policy Committee Director approval.
- 09/14/2022 Medical Policy Implementation Committee approval. No change to coverage.
- 03/02/2023 Medical Policy Committee Director approval.
- 03/08/2023 Medical Policy Implementation Committee approval. No change to coverage. Added intense pulsed light therapy to the note as not covered.
- 03/07/2024 Medical Policy Committee Director approval.
- 03/13/2024 Medical Policy Implementation Committee approval. No change to coverage.
- 11/07/2024 Medical Policy Committee Director approval.
- 11/13/2024 Medical Policy Implementation Committee approval. Added "Based on review of available data, the Company may consider vascular lesions to be eligible for coverage."

Patient Selection Criteria

Coverage eligibility for laser destruction of cutaneous vascular\* lesions will be considered when any of the following criteria are met:

- Congenital port-wine stains; OR
- Cutaneous hemangioma/hemangiomata (e.g., venous, arteriovenous, lymphatic)

## Note:

\* Hypertrophic burn scars, viral or plantar warts, and any other non-vascular skin lesion are not considered to be vascular proliferative lesions. Therefore, laser therapy for these conditions should not be reported with CPT codes 17106, 17107, or 17108.

Added Policy Guidelines also. Title changed from "Laser Treatment of Acne and Rosacea" to "Laser Treatment of Skin Conditions." Added Port wine stain information to body of policy.

Next Scheduled Review Date: 11/2025

# **Coding**

The five character codes included in the Louisiana Blue Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology  $(CPT^{\circledast})^{\ddagger}$ , copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character

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*identifying codes and modifiers for reporting medical services and procedures performed by physician.* 

The responsibility for the content of Louisiana Blue Medical Policy Coverage Guidelines is with Louisiana Blue and no endorsement by the AMA is intended or should be implied. The AMA disclaims responsibility for any consequences or liability attributable or related to any use, nonuse or interpretation of information contained in Louisiana Blue Medical Policy Coverage Guidelines. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein. Any use of CPT outside of Louisiana Blue Medical Policy Coverage Guidelines should refer to the most current Current Procedural Terminology which contains the complete and most current listing of CPT codes and descriptive terms. Applicable FARS/DFARS apply.

CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

| Code Type        | Code                       |
|------------------|----------------------------|
| СРТ              | 17106, 17107, 17108, 96920 |
| HCPCS            | No codes                   |
| ICD-10 Diagnosis | All related Diagnoses      |

\*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

- A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
- B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
  - 1. Consultation with technology evaluation center(s);
  - 2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
  - 3. Reference to federal regulations.

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\*\*Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

- A. In accordance with nationally accepted standards of medical practice;
- B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
- C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

**NOTICE:** If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

**NOTICE:** Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

**NOTICE:** Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.

