



# Louisiana

## Laser Treatment of Acne and Rosacea

**Policy #** 00162

**Original Effective Date:** 03/07/2005

**Current Effective Date:** 09/19/2018

*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.*

### **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**.\*

### **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. Low-fluence pulsed dye lasers are less ablative and purpuric and may be preferred in 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 a chronic, inflammatory skin condition that cannot be cured; the goal of treatment is symptom management. Nonpharmacologic treatments, including laser and light therapy, dermabrasion, and others, are proposed for patients who do not want to use or are unresponsive to pharmacologic treatments.

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 have a tendency to flush or blush easily. Since rosacea causes facial swelling and redness, it is easily confused with other skin conditions, such as acne, skin allergy, and sunburn.

Rosacea affects mostly 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, 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 is unknown but may be a result of both genetic and environmental factors. Some of the theories as to 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, there may be psychological consequences from the most visually apparent symptoms (i.e., erythema, papules, pustules, telangiectasias) that can 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 sufficiently great to warrant preventive removal of rhinophymatous tissue.

While rosacea cannot be eliminated, treatment can be effective to relieve its signs and symptoms. Treatment may include oral and topical antibiotics, isotretinoin, beta-blockers, 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. 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. Nonpharmacologic therapy has also been tried in patients who cannot tolerate or do not want to use pharmacologic treatments. The various lasers used include low-powered electrical devices and vascular light lasers to remove telangiectasias, CO2 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.

### **FDA or Other Governmental Regulatory Approval**

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

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### 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>™</sup> and CoolTouch<sup>®</sup>); intense pulsed light systems, which emit light in the range of 590 to 1200nm (Radiance ClearTouch<sup>™</sup>, MED flash II and Ellipse I<sup>2</sup>PL); 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>™</sup>, Clearlight and Dermillume). 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>™</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:

- Candela<sup>®</sup> pulse dye laser system (Candela, Wayland, MA)
- Lumenis<sup>®</sup> One Family of Systems IPL component (Lumenis, Santa Clara, CA)
- Harmony<sup>®</sup> XL multi-application platform laser device (Alma Lasers, Israel)
- UV-300 Pulsed Light Therapy System (New Star Lasers, Roseville, CA)
- CoolTouch PRIMA Pulsed Light Therapy System (New Star Lasers, Roseville, CA).

FDA product code: GEX.

Centers for Medicare and Medicaid Services (CMS)

### Acne

No national coverage determination.

### Rosacea

No national coverage determination.

## Rationale/Source

### 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

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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 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 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/cm<sup>2</sup> 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.

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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/cm<sup>2</sup> 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 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 ± 0.57 for Group A, 0.65 ± 0.47 for Group B, and 0.68 ± 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

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

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### Systematic Reviews

In 2015, a Cochrane systematic review was published by van Zuuren et al on a variety of interventions for rosacea. The systematic review identified 58 RCTs that compared treatments with placebo or a different intervention in adults with clinically diagnosed moderate to severe rosacea. The investigators identified only 4 trials on light therapy and/or laser therapy, and the trials did not compare these interventions with pharmacologic treatments or placebo controls. Findings of the trials on light and/or laser therapy were not pooled. The remainder of the RCTs in the Cochrane review evaluated pharmacologic treatments.

Other systematic reviews included RCTs, as well as uncontrolled studies. In 2014, Wat et al identified 9 studies on the efficacy of intense pulsed light (IPL) for treating rosacea. Two of the studies were controlled (left-right comparisons), and the remainder were uncontrolled, including 1 case report. A 2013 systematic review addressed pulsed dye laser (PDL) and identified 2 uncontrolled studies on PDL for treatment of rosacea. None of the systematic reviews pooled the findings of studies on nonpharmacologic treatment of rosacea. Findings of the published systematic reviews highlight the shortage of RCTs on light and laser therapy for treating rosacea.

### Randomized Controlled Trials

Several randomized trials on nonpharmacologic treatment for rosacea, as well as a small nonrandomized comparative study, all of which used split-faced designs, were identified. Most compared 2 types of lasers, and none used a placebo control or used a pharmacologic treatment as the comparison intervention. No RCTs evaluating dermabrasion, chemical peels, surgical debulking, or electrosurgery for treating rosacea were identified. Representative RCTs are described briefly next.

A 2013 double-blind study by Alam et al studied 16 patients with erythematotelangiectatic rosacea. Participants received PDL treatment on a randomly selected side of the face and neodymium-yttrium aluminum garnet (Nd:YAG) laser treatment on the other side. Treatments occurred at monthly intervals for 4 months. Fourteen of the 16 patients (88%) completed the study and were included in the analysis. The primary study outcome was the percent difference in facial redness (according to spectrophotometer measurements) from baseline to posttreatment. There was a mean difference in redness of 8.9% after PDL and a mean difference of 2.5% after Nd:YAG group; the difference between groups was statistically significant ( $p=0.02$ ). Pain ratings, however, were significantly higher with PDL (mean pain level, 3.9/10) compared with Nd:YAG (mean pain level, 3.1/10;  $p=0.003$ ).

In 2010, Maxwell and colleagues published a split-face design study that included 14 patients with acne rosacea. The study evaluated the combination of laser treatment and a topical treatment. All patients received 6 sessions of treatment with a 532 nm laser and a retinaldehyde-based topical application over 3 months on a randomly selected side of the face. The other side of the face served as the control. Eleven of 14 patients (79%) completed the study. At the end of the treatment period, blinded evaluators could correctly identify the treated side of the face 47% of the time (i.e., close to the 50% expected by chance). This was a small study with dropouts and involved limited collection of objective efficacy data.

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A 2009 study by Neuhaus et al included patients with moderate erythematotelangiectatic rosacea without active inflammatory papules and pustules. Twenty-nine patients were randomly assigned to receive treatment with a PDL on 1 side of the face and IPL on the other side, and 4 patients each received either PDL or IPL on 1 side of the face and no treatment on the other. Laterality of treatment (right vs left side) was also randomly assigned. Patients underwent a total of 3 treatment sessions, 4 weeks apart and received their final evaluation 4 weeks after the third treatment. Outcomes included an overall erythema score and overall telangiectasia score graded by a blinded observer and patient self-report of symptoms. Only p values, not actual scores were reported. There were no significant differences in outcomes between the PDL and IPL groups. Thus, we cannot conclude that one of these treatments is superior to the other. In this study, there were significantly lower erythema and telangiectasia scores for both IPL and PDL treatment compared with control ( $p < 0.01$ ). However, the comparisons with no treatment included only 4 patients each, and therefore these findings should be considered preliminary.

### Summary of Evidence

For individuals who have rosacea who receive nonpharmacologic treatment (eg, laser therapy, light therapy, dermabrasion), the evidence includes several small randomized, split-face design trials. Relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. None of the RCTs included a comparison group of patients receiving a placebo or pharmacologic treatment; therefore, these trials do not offer definitive evidence on the efficacy of nonpharmacologic treatment compared with alternative treatments. There is a need for RCTs that compare nonpharmacologic treatments with placebo controls and with pharmacologic treatments. The evidence is insufficient to determine the effects of the technology on health outcomes.

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# Louisiana

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Policy # 00162

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### Policy History

Original Effective Date: 03/07/2005

Current Effective Date: 09/19/2018

- |            |                                                                                                                                                                                   |
|------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 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.                                                                                                          |

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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.  
 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.  
 Next Scheduled Review Date: 09/2019

### Coding

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| Code Type        | Code                                     |
|------------------|------------------------------------------|
| CPT              | 17110, 17111                             |
| HCPCS            | No codes                                 |
| ICD-10 Diagnosis | L70.0-L70.9, L70.10-L70.19, L73.0, L90.5 |

\*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. 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

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# Louisiana

## Laser Treatment of Acne and Rosacea

Policy # 00162

Original Effective Date: 03/07/2005

Current Effective Date: 09/19/2018

- 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 the Blue Cross and Blue Shield Association technology assessment program (TEC) or other nonaffiliated 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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**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.

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