Laser Treatment of Acne and Rosacea

Policy #  00162
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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.

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.
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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 causing of rosacea are 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)

**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™ and CoolTouch®), intense pulsed light systems, which emit light in the range of 590 to 1200nm (Radiant ClearTouch™, MED flash II and Ellipse IPL); 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™, 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
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treatment of inflammatory acne or for mild to moderate acne with no location specified. In 2006, a thermal
device (ThermaClear™) 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. FDA through the
510(k) process for a variety of dermatologic indications, including rosacea. For example, rosacea is among
the indications for the Candela pulse dye laser system (Candela Corp.; Wayland, MA), the Lumenis One
Family of Systems intense pulsed light component (Lumenis Inc.; Santa Clara, Ca), and the Harmony XL
multi-application platform laser device (Alma Lasers; Israel).

Centers for Medicare and Medicaid Services (CMS)
Acne
No national coverage determination.

Rosacea
No national coverage determination.

Rationale/Source
Acne
An initial literature search of MEDLINE through September 2004 was conducted when the policy was
created. Since that time, the policy has been updated regularly with a literature review using MEDLINE;
most recently, the literature search was conducted from April 2008 through September 2009.

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 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 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 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...
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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
In 2011, van Zuuren and colleagues published a Cochrane systematic review on interventions for rosacea (an update of a 2005 review). The systematic review identified 58 RCTs that compared treatments to placebo or a different intervention in adults with clinically diagnosed moderate to severe rosacea. The investigators identified only 1 trial on light therapy and 1 trial on laser therapy, and the trials did not compare these interventions with pharmacologic treatments or placebo controls. The remainder of the RCTs evaluated pharmacologic treatments. The Cochrane review highlights the lack of evidence on light and laser therapy for treating rosacea, especially in comparison to nonpharmacologic treatments. In addition, as the authors noted, additional trials evaluating nonpharmacologic therapies should be a priority because they have the potential to treat symptoms on the face, which is highly desirable.

The literature on nonpharmacologic treatment of rosacea primarily consists of case series. One of the largest series was published in 2011 by Kassir and colleagues who reviewed the medical records from 102 patients with mild to severe rosacea. All patients had their entire face treated with an intense pulsed light (IPL) system; the number of treatments and treatment parameters were individualized. Patients were evaluated pre-treatment and 1-2 weeks post-treatment. According to clinician assessment and photodocumentation, 80% of patients had reduced redness after treatment. Photodocumentation showed a 51% reduction in telangiectasia. The study did not include long-term follow-up. Another of the larger series was published in 2005 by Schroeter and colleagues in the Netherlands. The authors reported 77.8% long-term clearance (follow-up of 12–99 months) of telangiectasia in 60 randomly selected patients with facial rosacea who had been treated with IPL.

Two randomized trials, both using split-face designs, on nonpharmacologic treatment for rosacea were identified. Neither of these RCTs compared nonpharmacologic treatments with a placebo control or with pharmacologic treatment. A 2009 study by Neuhaus and colleagues included patients with moderate erythematotelangiectatic rosacea without active inflammatory papules and pustules. Patients were at least 18 years of age and had not received previous treatment with a laser or light-based device, were not undergoing treatment with a photosensitizing agent, and had not had changes to their medication in the past 3 months. Twenty-nine patients were randomly assigned to receive treatment with a pulsed dye laser (PDL, Vbeam, Candela Corp) on one side of the face and an intense pulsed light (IPL, Quantum, Lumenis) on the other side, and 4 patients each received either PDL or IPL on one side of the face and no treatment on the other. Laterality of treatment (right versus 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
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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. To determine whether both are effective or ineffective, studies with a control group are needed. In this study, there were significantly lower erythema and telangiectasia scores for both IPL and PDL treatment compared to control (p<0.01). However, the comparisons with no treatment included only 4 patients each, and therefore these findings should be considered preliminary.

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 drop-outs and involved limited collection of objective efficacy data.

Laser surgery is discussed on the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS) health information website (last updated in 2009) as a treatment option for red lines caused by dilated blood vessels or for rhinophyma. Thus, although phototherapy, either alone or in combination with aminolevulinic or methylaminolevulinic acid, appears to be an increasingly accepted and effective mode of treatment for rosacea and other skin disorders, there are no high-quality studies that compare this treatment approach with placebo or other topical therapies. In addition, standard practice guidelines for phototherapy have not been established.

Ongoing Clinical Trials
A search of the online Clinicaltrials.gov database in October 2012 did not identify any active comparative trials evaluating nonpharmacologic treatments for rosacea.

Summary
The evidence to date remains insufficient to conclude that nonpharmacologic treatment for rosacea improves health outcomes. Limited evidence from case series report short-term improvements in redness and telangiectasias. Two small randomized split-face design studies using laser therapy have been published, but these compare different methods of laser treatment and therefore do not offer useful evidence on the efficacy of nonpharmacologic treatment compared to alternative treatment options. As a result, there is a need for further RCTs comparing nonpharmacologic treatments to placebo controls and to pharmacologic treatments. Thus, nonpharmacologic treatments for rosacea are considered investigational.

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

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ICD-9 Diagnosis 695.3, 706.0, 706.1, 709.2
ICD-9 Procedure 86.3

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12/14/2004 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.
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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.
Next Scheduled Review Date: 07/2015

*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:

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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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