Nonpharmacologic treatment of rosacea, including but not limited to laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery, is considered investigational.

See the Codes table for details.

State or federal mandates (e.g., Federal Employee Program) may dictate that certain U.S. Food and Drug Administration–approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only by their medical necessity.

Plans may want to examine specific contract language regarding the definitions of cosmetic services to determine whether contract or benefit exclusions may apply to the treatment of rosacea.
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, 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) that may impact the 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.

Treatment

Rosacea treatment can be effective to relieve its signs and symptoms. Treatment may include oral and topical antibiotics, isotretinoin, β-blockers, clonidine, and anti-inflammatory agents. 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, 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.

REGULATORY STATUS

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® pulse dye laser system (Candela, Wayland, MA)
- Lumenis® One Family of Systems IPL component (Lumenis, Santa Clara, CA)
- Harmony® 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.

RATIONALE

This evidence review was created in November 2004 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through October 1, 2018.
Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the 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 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 a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and 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.

**nonpharmacologic treatment of Rosacea**

**Clinical Context and Therapy Purpose**

The purpose of nonpharmacologic treatments is to provide a treatment option in patients who have rosacea and do not want to use or are unresponsive to pharmacologic therapies.

The question addressed in this evidence review is: Does the use of nonpharmacologic treatments improve the net health outcome in individuals with rosacea compared with pharmacologic treatments?

The following PICOTS were used to select literature to inform this review.

**Patients**

The relevant population of interest are individuals with rosacea.

**Interventions**

Nonpharmacologic treatment options include laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery. During laser and light therapy, light energy is absorbed by hemoglobin in cutaneous vessels, which leads to vessel heating and coagulation. Lasers vary from low-powered electrical devices and vascular light lasers (for telangiectasias removal) to co2 lasers and intense pulsed lights that generate multiple wavelengths to treat a broader spectrum of tissue.

Frequency and duration of laser and light therapy sessions varies, from once to twice per month, for several months. Because light-based techniques do not cure rosacea, periodic treatments may be necessary to maintain symptom relief.

**Comparators**

The comparators of interest are pharmacologic therapies, which include oral and topical antibiotics, isotretinoin, β-blockers, clonidine, and anti-inflammatories.

**Outcomes**
The general outcome of interest is symptom reduction, which may include a change in redness of skin color or change in erythema score or telangiectasia score. Other outcomes of interest include a reduction in pain, subject satisfaction, and improvement in the quality of life.

Timing

Outcome measures can be assessed on treatment completion. Because laser and light therapy are not curative, outcomes can be measured months after treatment to assess symptom recurrence.

Setting

Laser and light therapy are administered in outpatient settings.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
- To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow up and/or larger populations were sought.
- Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

A Cochrane systematic review by van Zuuren et al (2015) assessed various interventions for rosacea. Reviewers identified 106 RCTs that compared treatments with placebo or a different intervention in adults with clinically diagnosed moderate-to-severe rosacea. They identified only four trials on light and/or laser therapy, and the trials did not compare these interventions with pharmacologic treatments or placebo controls. Trial findings on light and/or laser therapy were considered low quality and were not pooled. The remainder of the RCTs in the review evaluated pharmacologic treatments.

Other systematic reviews have included RCTs as well as uncontrolled studies. Wat et al (2014) identified 9 studies on the efficacy of intense pulsed light (IPL) for treating rosacea. Two studies were controlled (left-right comparisons), and the remainder were uncontrolled, including a case report. A systematic review by Erceg et al (2013) assessed pulsed dye laser (PDL) and identified 2 uncontrolled studies on PDL for treatment of rosacea. None of the systematic reviews pooled study findings 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 and Nonrandomized Controlled Trials

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

A double-blind, randomized study by Alam et al (2013) studied 16 patients with erythematotelangiectatic rosacea. Participants received PDL treatment on a randomly selected side of the face and neodymium-yttrium aluminum garnet) laser treatment on the other side. Treatments
occurred at monthly intervals for four months. Fourteen (88%) of the 16 patients completed the trial 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 the neodymium-yttrium aluminum garnet 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) than with the neodymium-yttrium aluminum garnet (mean pain level, 3.1/10; p=0.003).

Maxwell et al (2010) reported on 14 patients who had 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 a no treatment control. Eleven (79%) of 14 patients completed the study. At the end of treatment, blinded evaluators could correctly identify the treated side of the face 47% of the time (ie, close to the 50% expected by chance). This small study had a limited collection of objective efficacy data.

A randomized, split-face design study by Neuhaus et al (2009) included patients with moderate erythematotelangiectatic rosacea without active inflammatory papules and pustules. Twenty-nine patients were randomized to PDL on one side of the face and IPL on the other side, and four patients each received either PDL or IPL on one side of the face and no treatment on the other. Laterality of treatment (right vs left side) was also randomized. Patients underwent three treatment sessions, four weeks apart, and received their final evaluation four 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. In this study, erythema and telangiectasia scores for both IPL and PDL treatment groups were significantly lower compared with the control treatment (p<0.01). However, the comparison with no treatment included only four 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. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. The randomized controlled trials evaluated laser and light therapy. No trials assessing other nonpharmacologic treatments were identified. None of the randomized controlled trials included a comparison group of patients receiving a placebo or pharmacologic treatment; therefore, these trials do not offer evidence on the efficacy of laser or light treatment compared with alternative treatments. There is a need for randomized controlled trials 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.

**SUPPLEMENTAL INFORMATION**

**Practice Guidelines and Position Statements**

**American Acne and Rosacea Society**

The American Acne and Rosacea Society (2014) issued consensus recommendations on the management of rosacea. The Society stated that lasers and intensely pulsed light 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.

**American Academy of Dermatology**

The AAD (2017) released online guidance for treatment and management of rosacea. The AAD encouraged patients to identify their triggers to minimize symptoms, including protection from exposure to the sun, heat, stress, alcohol, and spicy foods. The AAD indicated that laser or light therapy may be used to reduce redness and that laser resurfacing may be used to remove thickening skin. The AAD also stated that “researchers continue to study how lasers and light treatments can treat rosacea. As we learn more, these devices may play a bigger role in treating rosacea.”

**Rosacea Consensus Panel**

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

**National Institutes for Health and Care Excellence**

The National Institutes for Health and Care Excellence (2017) published online pathways addressing skin damage and skin conditions. Pathways provide guidance on the use of topical agents to manage rosacea. There are no pathways, guidance, or recommendations on nonpharmacologic treatments for rosacea.

**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 unpublished trials that might influence this review are listed in Table 1.

**Table 1. Summary of Key Trials**

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<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
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<td>Evaluation Of The Effect Of The Perfecta V-Beam Laser On Rosacea (Facial Redness, Telangiectasias And Photodamage)</td>
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<td>NCT03194698</td>
<td>Efficacy of Intense Pulsed Light Treatment of Dry Eye and Ocular Rosacea</td>
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<td>NCT02075671^a</td>
<td>Photodynamic Therapy</td>
<td>30</td>
<td>Feb 2019</td>
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NCT: national clinical trial.

*Denotes industry-sponsored or cosponsored trial.

**ESSENTIAL HEALTH BENEFITS**

The Affordable Care Act (ACA) requires fully insured non-grandfathered individual and small group benefit plans to provide coverage for ten categories of Essential Health Benefits (“EHBs”), whether the benefit plans are offered through an Exchange or not. States can define EHBs for their respective state. States vary on how they define the term small group. In Idaho, a small group employer is defined as an employer with at least two but no more than fifty eligible employees on the first day of the plan or contract year, the majority of whom are employed in Idaho. Large group employers, whether they are self-funded or fully insured, are not required to offer EHBs, but may voluntary offer them.

The Affordable Care Act requires any benefit plan offering EHBs to remove all dollar limits for EHBs.

**REFERENCES**


**CODES**

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<thead>
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<th>Codes</th>
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<td>Dermabrasion, face code range</td>
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<td>15788-15793</td>
<td>Chemical peel code range</td>
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<td>17000-17004</td>
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<td>17106-17108</td>
<td>Destruction of cutaneous vascular proliferative lesions (eg, laser technique) code range</td>
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### Nonpharmacologic Treatment of Rosacea

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### POLICY HISTORY

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