Nonpharmacologic Treatment of Rosacea

Description

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 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 rosacea, 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.

**Regulatory Status**

Several laser and light therapy 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 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).

**Related Policies**

2.01.47 Targeted Phototherapy for Psoriasis
8.01.16 Chemical Peels

**Policy**

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

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

**Rationale**

Randomized, controlled trials (RCTs) are crucial in determining the efficacy of nonpharmacologic treatment of rosacea and whether or not treatment improves the net health outcome. Ideally, RCTs would compare nonpharmacologic treatments with a placebo or a pharmacologic treatment. Where RCTs are lacking, non-randomized comparative studies provide some evidence for efficacy but are limited by potential selection bias because patients may be preferentially selected for one treatment over another by disease severity or other clinical factors. Uncontrolled trials and case series offer little useful evidence on the efficacy of nonpharmacologic treatments. This review focuses on RCTs and systematic reviews of RCTs.

**Nonpharmacologic Treatments of Rosacea**

**Systematic reviews:**

In 2015, a Cochrane systematic review was published by van Zuuren et al on a variety of interventions for rosacea. (1) The systematic review identified 106 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 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. (2) 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. (3) 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 Control 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. (4-8) Most compared 2 types of lasers, and none used a placebo control or used a pharmacologic treatment as the comparison intervention. There were no RCTs evaluating dermabrasion, chemical peels, surgical debulking, or electrosurgery for treating rosacea identified. Representative RCTs are described briefly next.

A 2013 double-blind study by Alam et al studied 16 patients with erythematotelangiectatic rosacea.4 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 post treatment. 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 reported on 14 patients who had acne rosacea. (5) 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 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.

A 2009 study by Neuhaus and colleagues included patients with moderate erythematotelangiectatic rosacea without active inflammatory papules and pustules. (6) Twenty-nine patients were randomly assigned to receive treatment with a pulsed dye laser on one side of the face and an intense pulsed light (IPL) 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 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 to control (p<0.01). However, the comparisons with no treatment included only 4 patients each, and therefore these findings should be considered preliminary.

**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**

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
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<td>NCT02204254</td>
<td>RosaC-RF : Bipolar Radiofrequency vs Doxycycline in Rosacea</td>
<td>40</td>
<td>Jun 2015&lt;sup&gt;b&lt;/sup&gt;</td>
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<tr>
<td>NCT02075671&lt;sup&gt;a&lt;/sup&gt;</td>
<td>Photodynamic Therapy for Papulopustular Rosacea</td>
<td>30</td>
<td>Dec 2015</td>
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NCT: national clinical trial.
<sup>a</sup> Denotes industry-sponsored or cosponsored trial.
<sup>b</sup> Trial continues to recruit patients despite estimated completion date.

**Practice Guidelines and Position Statements**

A search of the National Guideline Clearinghouse database did not identify any guidelines or position statements from national organizations on the use of nonpharmacologic treatments for treating rosacea.

**Summary of the Evidence**

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

**Medicare National Coverage**

No national coverage determination.
References


Policy History

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<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>December 2011</td>
<td>New Policy</td>
<td>Policy updated with literature review through September, references updated, statement changed to Not Medically Necessary.</td>
</tr>
<tr>
<td>March 2013</td>
<td>Update Policy</td>
<td>Policy updated with literature review through September, references updated, statement changed to Not Medically Necessary.</td>
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<td>March 2014</td>
<td>Update Policy</td>
<td>Policy updated with literature review, adding references 2, 3, 6, and 11. Literature review reorganized. No change to policy statement.</td>
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<td>March 2015</td>
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<td>June 2016</td>
<td>Update Policy</td>
<td>Policy updated with literature review through November 10, 2015; reference 1 added. Policy statement unchanged</td>
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Keywords

Rosacea, Treatment of Laser Treatment, Rosacea

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 24, 2016 and is effective July 15, 2016.

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