Non-Pharmacologic Treatment of Rosacea

Policy Number: 2.01.71  Last Review: 5/2017

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will not provide coverage for non-pharmacologic treatment of rosacea. This is considered investigational.

When Policy Topic is covered
Not Applicable

When Policy Topic is not covered
Non-pharmacologic treatment of rosacea, including but not limited to laser and light therapy, dermabrasion, chemical peels, surgical debulking and electrosurgery, is considered investigational.

Description of Procedure or Service

<table>
<thead>
<tr>
<th>Populations</th>
<th>Interventions</th>
<th>Comparators</th>
<th>Outcomes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Individuals: With rosacea</td>
<td>Interventions of interest are: • Nonpharmacologic treatment (eg, laser therapy, light therapy, dermabrasion, others)</td>
<td>Comparators of interest are: • Pharmacologic treatment • Another type of nonpharmacologic treatment</td>
<td>Relevant outcomes include: • Symptoms • Change in disease status • Treatment-related morbidity</td>
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</table>

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 therapy.

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.

**Background**

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 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-inflammatory drugs. 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 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).

**Rationale**

This evidence review was originally created in November 2004 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through November 7, 2016. Following is a summary of the key literature to date.

Randomized controlled trials (RCTs) are crucial in determining the efficacy of nonpharmacologic treatment of rosacea and whether treatment improves the net health outcome. Ideally, RCTs would compare nonpharmacologic treatments with a placebo or a pharmacologic treatment. Where RCTs are lacking, nonrandomized comparative studies provide some evidence for efficacy but are limited by potential selection bias because patients may be preferentially selected for 1 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.

**Systematic Reviews**

In 2015, a Cochrane systematic review by van Zuuren et al 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 4 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 not pooled. The remainder of the RCTs in the review evaluated pharmacologic treatments.

Other systematic reviews have 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 studies were controlled (left-right comparisons), and the remainder were uncontrolled, including 1 case report. A 2013 systematic review 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 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 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 2013 double-blind, randomized 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 (88%) of the 16 patients 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) than with Nd:YAG (mean pain level, 3.1/10; p=0.003).

In 2010, Maxwell et al 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 limited collection of objective efficacy data.

A 2009 randomized, split-face design study by Neuhaus et al included patients with moderate erythematotelangiectatic rosacea without active inflammatory papules and pustules. Twenty-nine patients were randomized to 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 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, 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 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 randomized controlled trials (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.

Supplemental Information

Practice Guidelines and Position Statements

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

U.S. Preventive Services Task Force Recommendations
Not applicable.

Medicare National Coverage
There is no national coverage determination (NCD). In the absence of an NCD, 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

<table>
<thead>
<tr>
<th>NCT No.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ongoing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02075671</td>
<td>Photodynamic Therapy for Papulopustular Rosacea</td>
<td>30</td>
<td>Aug 2016 (ongoing)</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT02204254</td>
<td>RosaC-RF : Bipolar Radiofrequency vs Doxycycline in Rosacea</td>
<td>40</td>
<td>Jun 2015 (unknown)</td>
</tr>
<tr>
<td>NCT02268474</td>
<td>Excel V 532 nm KTP Laser for Treatment of Erythematotelangiectatic Rosacea and Papulopustular Rosacea</td>
<td>22</td>
<td>Aug 2015 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.

* Denotes industry-sponsored or cosponsored trial.
References


Billing Coding/Physician Documentation Information

15780 Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)

15781 Dermabrasion; segmental, face

15782 Dermabrasion; regional, other than face

15783 Dermabrasion; superficial, any site (eg, tattoo removal)

15788 Chemical peel, facial; epidermal

15789 Chemical peel, facial; dermal

15792 Chemical peel, nonfacial; epidermal

15793 Chemical peel, nonfacial; dermal

17000 Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettlement), premalignant lesions (eg, actinic keratoses); first lesion

17003 Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettlement), premalignant lesions (eg, actinic keratoses); second through 14 lesions, each (List separately in addition to code for first lesion)

17004 Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettlement), premalignant lesions (eg, actinic keratoses), 15 or more lesions

17106 Destruction of cutaneous vascular proliferative lesions (eg, laser technique); less than 10 sq cm

17107 Destruction of cutaneous vascular proliferative lesions (eg, laser
17108  Destruction of cutaneous vascular proliferative lesions (eg, laser technique); 10.0 to 50.0 sq cm
30117  Excision or destruction (eg, laser), intranasal lesion; internal approach
30118  Excision or destruction (eg, laser), intranasal lesion; external approach (lateral rhinotomy)

ICD10 Codes
L71.0-  Rosacea code range
L71.9

Additional Policy Key Words
N/A

Policy Implementation/Update Information
5/1/10  No policy statement changes.
5/1/11  No policy statement changes.
5/1/12  No policy statement changes.
5/1/13  No policy statement changes.
5/1/14  No policy statement changes.
5/1/15  No policy statement changes.
5/1/16  No policy statement changes.
5/1/17  No policy statement changes.

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