Nonpharmacologic Treatment of Rosacea
Corporate Medical Policy

File name: Nonpharmacologic Treatment of Rosacea
File code: UM.SURG.11
Last Review: 08/2016
Next Review: 08/2017
Effective Date: 09/01/2016

Description/Summary

Rosacea is a chronic, inflammatory skin condition without a known cure; 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 (e.g., 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.

<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 (e.g., 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>
</tr>
</tbody>
</table>
Policy

Coding Information

Click the links below for attachments, coding tables & instructions.

Attachment I - Code Table & Instructions

When a service is considered investigational

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

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. Because 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 (ie, 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, β-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.

Rationale/Scientific Background

This evidence review was originally created in 2004 and has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through November 10, 2015. Following is a summary of the key literature to date.

Nonpharmacologic Treatments of Rosacea

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, nonrandomized 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.

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 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. 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 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 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 (ie, close to the 50% expected by chance). This was a small study with dropouts and involved limited collection of objective efficacy data.

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.

**Ongoing and Unpublished Clinical Trials**

Some currently unpublished trials that might influence this review are listed in Table 1.

<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>NCT02204254</td>
<td>RosaC-RF : Bipolar Radiofrequency vs Doxycycline in Rosacea</td>
<td>40</td>
<td>Jun 2015b</td>
</tr>
<tr>
<td>NCT02075671*</td>
<td>Photodynamic Therapy for Papulopustular Rosacea</td>
<td>30</td>
<td>Dec 2015</td>
</tr>
</tbody>
</table>

*Ongoing and unpublished clinical trials listed in Table 1.*
NCT: national clinical trial.

a Denotes industry-sponsored or cosponsored trial.
b Trial continues to recruit patients despite estimated completion date.

Summary of 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.

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 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 IPL component (Lumenis Inc., Santa Clara, CA), and the Harmony® XL multiapplication platform laser device (Alma Lasers, Israel).

Reference Resources

Document Precedence

Blue Cross and Blue Shield of Vermont (BCBSVT) Medical Policies are developed to provide clinical guidance and are based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. The applicable group/individual contract and member certificate language, or employer’s benefit plan if an ASO group, determines benefits that are in effect at the time of service. Since medical practices and knowledge are constantly evolving, BCBSVT reserves the right to review and revise its medical policies periodically. To the extent that there may be any conflict between medical policy and contract/employer benefit plan language, the member’s contract/employer benefit plan language takes precedence.

Audit Information

BCBSVT reserves the right to conduct audits on any provider and/or facility to ensure compliance with the guidelines stated in the medical policy. If an audit identifies instances of non-compliance with this medical policy, BCBSVT reserves the right to recoup all non-compliant payments.

Administrative and Contractual Guidance

Benefit Determination Guidance

Prior approval is required for services as outlined in this policy. Benefits are subject to all terms, limitations and conditions of the subscriber contract.

An approved referral authorization for members of the New England Health Plan (NEHP) is required. A prior approval for Access Blue New England (ABNE) members is required. NEHP/ABNE members may have different benefits for services listed in this policy. To confirm benefits, please contact the customer service department at the member’s health plan.

Federal Employee Program (FEP): Members may have different benefits that apply. For further information please contact FEP customer service or refer to the FEP Service Benefit Plan Brochure. It is important to verify the member’s benefits prior to providing the service to determine if benefits are available or if there is a specific exclusion in the member’s benefit.

Coverage varies according to the member’s group or individual contract. Not all groups are required to follow the Vermont legislative mandates. Member Contract language takes precedence over medical policy when there is a conflict.

If the member receives benefits through an Administrative Services only (ASO) only group, benefits may vary or not apply. To verify benefit information, please refer to the member’s employer benefit plan documents or contact the customer service.
department. Language in the employer benefit plan documents takes precedence over medical policy when there is a conflict.

**Policy Implementation/Update information**

<table>
<thead>
<tr>
<th>Date</th>
<th>Update Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>08/2016</td>
<td>New Policy. Adopted BCBSA MPRM# 2.01.71.</td>
</tr>
</tbody>
</table>

**Eligible providers**

Qualified healthcare professionals practicing within the scope of their license(s).

**Approved by BCBSVT Medical Directors**

Joshua Plavin, MD  
Senior Medical Director  
Chair, Health & Payment Policy Committee

Robert Wheeler MD  
Chief Medical Officer

**Attachment I**

**Code Table & Instructions**

<table>
<thead>
<tr>
<th>Code Type</th>
<th>Number</th>
<th>Description</th>
<th>Policy Instructions</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT</td>
<td>15780</td>
<td>Dermabrasion; total face (eg, for acne scarring, fine wrinkling, rhytids, general keratosis)</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td></td>
<td>15781</td>
<td>Dermabrasion; segmental, face</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td></td>
<td>15782</td>
<td>Dermabrasion; regional, other than face</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td></td>
<td>15783</td>
<td>Dermabrasion; superficial, any site (eg, tattoo removal)</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>CPT</td>
<td>15788</td>
<td>Chemical peel, facial; epidermal</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td></td>
<td>15789</td>
<td>Chemical peel, facial; dermal</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td></td>
<td>15792</td>
<td>Chemical peel, nonfacial; epidermal</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td></td>
<td>15793</td>
<td>Chemical peel, nonfacial; dermal</td>
<td>Prior Approval Required</td>
</tr>
<tr>
<td>CPT</td>
<td>Description</td>
<td>Prior Approval Required</td>
<td></td>
</tr>
<tr>
<td>-------</td>
<td>----------------------------------------------------------------------------</td>
<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>17000-17004</td>
<td>Destruction (eg, laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettement), all benign or premalignant lesions (eg, actinic keratosis) other than skin tags or cutaneous vascular proliferative lesions code range</td>
<td>Prior Approval Required</td>
<td></td>
</tr>
<tr>
<td>17106-17108</td>
<td>Destruction of cutaneous vascular proliferative lesions (eg, laser technique) code range</td>
<td>Prior Approval Required</td>
<td></td>
</tr>
<tr>
<td>30117</td>
<td>Excision or destruction (eg, laser), intranasal lesion; internal approach</td>
<td>No Prior Approval Required</td>
<td></td>
</tr>
<tr>
<td>30118</td>
<td>Excision or destruction (eg, laser), intranasal lesion; external approach (lateral rhinotomy)</td>
<td>No Prior Approval Required</td>
<td></td>
</tr>
<tr>
<td>ICD-10-CM</td>
<td>Investigational for all relevant diagnoses</td>
<td></td>
<td></td>
</tr>
<tr>
<td>L71.0-L71.9</td>
<td>Rosacea code range</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Type of Service**: Medicine  
**Place of Service**: Outpatient