Non-Pharmacologic Treatment of Rosacea

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Replaces 2.01.71

Policy

Non-pharmacologic treatment of rosacea using laser may be considered medically necessary when the following criteria are met:

- Patient has tried and failed an adequate pharmacologic trial, defined as the use of 2 or more topical medications and/or oral antibiotics for at least 6 months AND
- Patient has developed complications of the disease and has physical functional impairments, such as:
  - Recurrent and/or persistent bacterial infections that have failed multiple courses of antibiotics
  - Persistent open wounds, or localized skin hemorrhage with associated bloody drainage;
  - Rhinophyma with nasal obstruction, airway impairment or sinus infection.

Non-pharmacologic treatment of rosacea using laser is considered not medically necessary when criteria are not met.

Related Policies

10.01.514 Cosmetic and Reconstructive Services

Policy Guidelines

Definition of Terms

Cosmetic: Cosmetic services are those which are primarily intended to preserve or improve appearance. Cosmetic surgery is performed to reshape structures of the body in order to improve the patient’s appearance or self-esteem.

Physical Functional Impairment: In this policy, functional impairment means a limitation from normal (or baseline level) of physical functioning that may include, but is not limited to, problems with ambulation, mobilization, communication, respiration, eating, swallowing, vision, facial expression, skin integrity, distortion of
nearby body parts or obstruction of an orifice. The physical functional impairment can be due to structure, congenital deformity, pain, or other causes. Physical functional impairment excludes social, emotional and psychological impairments or potential impairments.

Reconstructive Surgery: In this policy, reconstructive surgery refers to surgeries performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function.

Rhinophyma: Uncommon form of rosacea characterized by a large, red, bumpy nose. Symptoms include hyperplasia and nodular swelling and congestion of the skin of the nose. It is sometimes called “bulbous nose.”

<table>
<thead>
<tr>
<th>Coding</th>
<th>CPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>17106</td>
<td>Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq. cm</td>
</tr>
<tr>
<td>17107</td>
<td>Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); 10.0 to 50.0 sq. cm</td>
</tr>
<tr>
<td>17108</td>
<td>Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq. cm</td>
</tr>
</tbody>
</table>

Description

Rosacea is a chronic, inflammatory skin condition without a known cure. The goal of rosacea treatment is symptom management. Nonpharmacologic treatments, including laser and light therapy as well as dermabrasion, are proposed for patients who are unresponsive to pharmacologic therapy or have a contraindication to this therapy.

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 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 hyperplasia and nodular swelling and congestion of the skin of the nose (rhinophyma). The etiology and pathogenesis of rosacea is 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 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 strong enough to warrant preventive removal of rhinophymatous tissue.

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 drugs. 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 (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)
- CoolTouch® PRIMA Pulsed Light Therapy System (New Star Lasers, Roseville, CA)
- Harmony® XL multi-application platform laser device (Alma Lasers, Israel)
- Lumenis® One Family of Systems IPL component (Lumenis, Santa Clara, CA)
- UV-300 Pulsed Light Therapy System (New Star Lasers, Roseville, CA)

FDA product code: GEX.

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**Scope**

Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations. This medical policy does not apply to Medicare Advantage.

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**Benefit Application**

N/A

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**Rationale**

This policy 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 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. \(^1\) 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. \(^2\) Two studies were controlled (left-right...
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. (4-8) 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. (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 (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. (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 (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 (i.e., 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. (6) 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.

Ongoing and Unpublished Clinical Trials
A search of the online site ClinicalTrials.gov found the following trials 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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</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>
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<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</td>
<td>22</td>
<td>Aug 2015 (completed)</td>
</tr>
</tbody>
</table>

NCT: national clinical trial.
* Denotes industry-sponsored or cosponsored trial.

**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.(9) 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**

N/A

**Medicare National Coverage**

There is no national coverage determination.

**References**

Appendix

N/A

History

<table>
<thead>
<tr>
<th>Date</th>
<th>Reason</th>
</tr>
</thead>
<tbody>
<tr>
<td>02/08/05</td>
<td>Add to Medicine Section - New Policy. Held for notification, published 6/15/05.</td>
</tr>
<tr>
<td>02/14/06</td>
<td>Replace policy. Policy statement clarified with the removal of first sentence; last paragraph under Rationale also removed as they both referred to cosmetic. Policy will be reviewed again with BCBSA scheduled update.</td>
</tr>
<tr>
<td>02/22/06</td>
<td>Code updates. No other changes, effective date unchanged.</td>
</tr>
<tr>
<td>06/16/06</td>
<td>Update Scope and Disclaimer - No other changes.</td>
</tr>
<tr>
<td>12/12/06</td>
<td>Replace policy. Policy updated with literature review; references added; no change in policy statement.</td>
</tr>
<tr>
<td>07/10/07</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>11/11/08</td>
<td>NEW PR Policy 2.01.519 - Policy updated with literature search. Policy statement regarding rosacea changed from investigational to medically necessary. Status changed from BC to PR. Replaces BC.2.01.71. References added.</td>
</tr>
<tr>
<td>08/11/09</td>
<td>Replace policy. Policy updated with literature review; no change in policy statement.</td>
</tr>
<tr>
<td>02/09/10</td>
<td>Cross Reference Update - No other changes.</td>
</tr>
<tr>
<td>08/10/10</td>
<td>Replace policy. Policy updated with literature review; references added. No change to the policy statement.</td>
</tr>
<tr>
<td>07/12/11</td>
<td>Replace policy. Policy updated with literature review. No change to the policy statement.</td>
</tr>
<tr>
<td>09/23/11</td>
<td>Related Policies updated; 10.01.514 added.</td>
</tr>
<tr>
<td>02/14/12</td>
<td>Replace policy. Policy updated with literature review. No change to the policy statement.</td>
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<tr>
<td>02/13/13</td>
<td>Replace policy. Policy updated with literature review. No change to the policy statement.</td>
</tr>
<tr>
<td>03/15/13</td>
<td>Update Related Policies. Remove 2.01.521 as it was archived.</td>
</tr>
<tr>
<td>07/16/13</td>
<td>Update Related Policies. Add 2.01.89.</td>
</tr>
<tr>
<td>12/03/13</td>
<td>Coding Update. Add ICD-10 codes.</td>
</tr>
<tr>
<td>02/24/14</td>
<td>Replace policy. Policy updated with literature review. No change to the policy statement. CPT codes 17000 – 17004 and 30117 – 30118 were provided for informational purposes only and have been removed from the policy. ICD-9 Diagnosis code 695.3 was also removed from the policy, as it is not utilized in adjudicating the policy.</td>
</tr>
<tr>
<td>10/13/14</td>
<td>Interim Review. Change statement indicating that in the absence of failure of conservative treatment and complications of the disease resulting in a physical functional impairment, non-pharmacologic treatment of rosacea is considered cosmetic; previously it was stated to be not medically necessary.</td>
</tr>
<tr>
<td>02/25/15</td>
<td>Annual Review. Policy updated with literature review. No change to the policy statement. Reference added. ICD-9 and ICD-10 diagnosis and procedure codes removed; these are not utilized in policy adjudication.</td>
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<tr>
<td>08/31/15</td>
<td>Update Related Policies. Remove 2.01.89 as it was archived.</td>
</tr>
<tr>
<td>02/09/16</td>
<td>Annual Review. Updated clinical trials. Added reference 18. Coding update, removed CPT codes 15780-15783, 15788, 15789, 15792, and 15793. Removed HCPCS code S8948 as it is a non-covered service. The focus of this policy now is treatment with laser techniques, and policy statement revised.</td>
</tr>
<tr>
<td>03/01/17</td>
<td>Annual review, approved February 14, 2017. Policy updated with literature review through November 2016; reference added. Policy statement changed from cosmetic to not medically necessary when criteria are not met.</td>
</tr>
</tbody>
</table>
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Office for Civil Rights, 200 Independence Avenue SW, Room 509F, HHH Building
Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD)
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