Introduction

Rosacea is a long-lasting skin condition that affects adults. It usually affects more women than men. And while it can affect anyone, it usually occurs more frequently in people with fair skin. Typically, rosacea affects adults between the ages of 20 and 60. It often creates redness on the cheeks, nose, chin, or forehead. It can also affect the neck, chest, scalp, or ears. The redness tends to become more persistent over time, with little blood vessels appearing. Bumps and pimples may also develop. In some people, the nose becomes swollen or bumpy due to extra tissue. (This is known as rhinophyma.) While rosacea can’t be cured, medication (pharmacologic treatment) is effective in controlling symptoms. Other treatments, such as laser or light therapy or removing the top layers of the skin (dermabrasion), have been tried. These types of rosacea treatments are investigational (unproven). Published medical studies do not conclusively prove that they work as well as or better than using medication. More and longer studies are needed.

Note: The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.
Nonpharmacologic treatment of rosacea, including but not limited to laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery, is considered investigational.

### Coding

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

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### Related Information

N/A

### Evidence Review
Description

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 as well as dermabrasion, which are the focus of this policy, are proposed for patients who do not want to use or are unresponsive to pharmacologic therapy.

Background

Rosacea

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 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, telangiecstasias, 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, telangiecstasias) 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 sufficient to warrant preventive removal of rhinophymatous tissue.
Treatment

Rosacea treatment can be effective in relieving 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 such as laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery have been used. 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 (IPL) that generate multiple wavelengths to treat a broader spectrum of tissue.

Summary of Evidence

For individuals with rosacea who receive nonpharmacologic treatment (eg, laser therapy, light therapy, dermabrasion), the evidence includes systematic reviews and several small randomized, split-face design trials. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. The systematic reviews reported favorable effects on erythema and telangiectasia with several laser types, including IPL, pulsed dye lasers, and Nd:YAG lasers. However, the systematic reviews did not pool results from individual studies and the studies differed in the specific lasers being compared. Overall, the systematic review results were insufficient to establish whether any laser type is more effective and safe than others. 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.
Ongoing and Unpublished Clinical Trials

Some currently ongoing and 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>NCT04153188a</td>
<td>Pilot Study to Evaluate Vbeam® Prima Pulsed Dye Laser (PDL) Treatment and RHOFADE® (Oxymetazoline HCL, 1% Cream) for Erythematotelangiectatic Rosacea</td>
<td>60</td>
<td>July 2022 (ongoing)</td>
</tr>
<tr>
<td>Unpublished</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>NCT03194698</td>
<td>Efficacy of Intense Pulsed Light Treatment of Dry Eye and Ocular Rosacea</td>
<td>20</td>
<td>Dec 2018 (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 issued consensus recommendations on the management of rosacea.23 The Society stated that lasers and IPL 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.

In 2016, the American Acne and Rosacea Society issued updated consensus recommendations on the management of rosacea.24 The update focused on how medical and device therapies are used--whether concurrently or in a staggered fashion--noting that there is a lack of evidence to justify either use. The Society's consensus recommendation on rosacea management correlated with clinical manifestations observed at the time of presentation are summarized in Table 2.
Table 2. Recommendations on Use of Lasers and Intensely Pulse Light Devices for the Management of Rosacea

<table>
<thead>
<tr>
<th>Condition</th>
<th>Recommendation</th>
<th>Grade&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent central facial erythema without papulopustular lesions</td>
<td>IPL, potassium titanyl phosphate crystal laser, or pulsed-dye laser</td>
<td>B</td>
</tr>
<tr>
<td>Diffuse central facial erythema with papulopustular lesions</td>
<td>“While the data on the use of IPL, potassium titanyl phosphate or pulsed-dye laser are limited for papulopustular lesions, these options are useful to treat erythema”</td>
<td>NR</td>
</tr>
<tr>
<td>Granulomatous rosacea</td>
<td>Intense pulsed-dye laser</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>“No current standard of treatment; limited data based on case reports”</td>
<td></td>
</tr>
<tr>
<td>Phymatous Rosacea</td>
<td>“Surgical therapy for fully developed phymatous changed (carbon dioxide laser, erbium-doped [YAG] laser, electrosurgery, dermabrasion)”</td>
<td>C</td>
</tr>
<tr>
<td></td>
<td>“Treatment selection dependent on stage of development (early or fibrotic) and extent of inflammation (active or burnt out)”</td>
<td></td>
</tr>
</tbody>
</table>

IPL: intense pulsed light, YAG: yttrium aluminum garnet; NR: not reported.
<sup>a</sup> Grade A: Criteria not described in recommendation; Grade B: Systematic review/meta-analysis of lower-quality clinical trials or studies with limitations and inconsistent findings; lower-quality clinical trial; Grade C: Consensus guidelines; usual practice, expert opinion, case series—limited trial data

American Academy of Dermatology

In 2017, the American Academy of Dermatology (AAD) 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

In 2017, the Rosacea Consensus panel, 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.

The panel updated their recommendations on rosacea treatment in 2019, agreeing that lasers were recommended for persistent centrofacial erythema. They also noted that “use of IPL and vascular lasers in darker skin phototypes requires consideration by a healthcare provider with experience..., as it can result in dyspigmentation.” The panel also acknowledged that combining treatments could benefit patients with more severe rosacea and multiple rosacea features; however, “there remains an ongoing need for more studies to support combination treatment use in rosacea.”

National Rosacea Society

In 2019, the National Rosacea Society Executive Committee published an expert consensus document on management options for rosacea. This document endorses treatment goals of an Investigator Global Assessment score of 0 and normalization of skin tone and color due to the notable impact of rosacea on patient quality of life. Light devices are discussed as treatment options along with medications, skin care, and lifestyle interventions. Based on weak evidence, IPL, pulsed dye lasers, and potassium titanyl phosphate lasers are listed as moderately effective treatment options for persistent erythema, particularly due to telangiectasia. Both IPL and potassium titanyl phosphate are described as having at least some efficacy for flushing. Nonpharmacologic interventions that are listed as more highly effective treatment options for non-inflamed phymas (based on weak evidence) include carbon dioxide lasers, erbium lasers, cold steel, electrosurgery, and radiofrequency; these same interventions are listed for use in combination with other treatment modalities for inflammatory phymas. Carbon dioxide lasers, erbium lasers, cold steel, electrosurgery, and radiofrequency carry a risk of post-inflammatory hyperpigmentation and should only be provided by appropriately trained individuals.
National Institutes for Health and Care Excellence

In 2017, the National Institutes for Health and Care Excellence 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.

Medicare National Coverage

There is no national coverage determination.

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:

- Vbeam laser system (Candela)
- Stellar M22™ laser system (Lumenis)Harmony® XL multi-application platform laser device (Alma Lasers, Israel)
- UV-300 Pulsed Light Therapy System (New Star Lasers)
- CoolTouch® PRIMA Pulsed Light Therapy System (New Star Lasers).

FDA product code: GEX.

References


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**History**

<table>
<thead>
<tr>
<th>Date</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>03/01/18</td>
<td>Policy reinstated, approved February 13, 2018, effective June 1, 2018. This policy was previously deleted, but now replaces policy 2.01.519. Nonpharmacologic treatment of rosacea is considered investigational.</td>
</tr>
<tr>
<td>06/01/18</td>
<td>Minor update; removed note and link to previous policy 2.01.519 which has been deleted.</td>
</tr>
<tr>
<td>03/01/19</td>
<td>Annual Review, approved February 5, 2019. Policy updated with literature review through October 2018; references 11 added. Policy statement unchanged.</td>
</tr>
</tbody>
</table>
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  - Written information in other formats (large print, audio, accessible electronic formats, other formats)
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Email AppealsDepartmentInquiries@Premera.com

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U.S. Department of Health and Human Services
200 Independence Avenue SW, Room 509F, HHH Building

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