Policy Statement

Nonpharmacologic treatment of rosacea is considered investigational, including but not limited to the following:

- Chemical peels
- Dermabrasion
- Electrocoagulation
- Laser and light therapy
- Surgical debulking

Policy Guidelines

State or federal mandates (e.g., FEP) may dictate that certain U.S. Food and Drug Administration-approved devices, drugs, or biologics may not be considered investigational, and thus these devices may be assessed only on the basis of their medical necessity.

Coding

There are a variety of CPT codes that would likely be used for the nonpharmacologic treatment of rosacea:

- **15780**: Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)
- **15781**: Dermabrasion; segmental, face
- **15782**: Dermabrasion; regional, other than face
- **15783**: Dermabrasion; superficial, any site (e.g., tattoo removal)
- **15788**: Chemical peel, facial; epidermal
- **15789**: Chemical peel, facial; demal
- **15792**: Chemical peel, nonfacial; epidermal
- **15793**: Chemical peel, nonfacial; demal
- **17106**: Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); less than 10 sq cm
- **17107**: Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); 10.0 to 50.0 sq cm
- **17108**: Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq cm
- **30117**: Excision or destruction (e.g., laser), intranasal lesion; internal approach
- **30118**: Excision or destruction (e.g., laser), intranasal lesion; external approach (lateral rhinotomy)

The following HCPCS codes describe light therapy:

- **E0691**: Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 sq ft or less
- **E0692**: Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 4 ft panel
- **E0693**: Ultraviolet light therapy system panel, includes bulbs/lamps, timer and eye protection, 6 ft panel
- **E0694**: Ultraviolet multidirectional light therapy system in 6 ft cabinet, includes bulbs/lamps, timer, and eye protection
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 evidence review, are proposed for patients who do not want to use or are unresponsive to pharmacologic therapy.

Related Policies

- Chemical Peels
- Light Therapy for Psoriasis
- Targeted Phototherapy and Psoralen with Ultraviolet A for Vitiligo

Benefit Application

Benefit determinations should be based in all cases on the applicable contract language. To the extent there are any conflicts between these guidelines and the contract language, the contract language will control. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

Some state or federal mandates (e.g., Federal Employee Program [FEP]) prohibits plans from denying Food and Drug Administration (FDA)-approved technologies as investigational. In these instances, plans may have to consider the coverage eligibility of FDA-approved technologies on the basis of medical necessity alone.

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 various dermatologic indications, including rosacea. For example, rosacea is among the indications for:

- Candela® pulse dye laser system (Candela)
- Lumenis® One Family of Systems IPL component (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).

Food and Drug Administration product code: GEX.

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of technology improves the net health outcome. Broadly defined, health outcomes are the length of life, quality of life, and ability to function—including benefits and harms. Every clinical condition has specific outcomes that are important to patients and managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of technology, two domains are examined: the relevance, and quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality
and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice. The following is a summary of the key literature to date.

**Nonpharmacologic Treatment of Rosacea**

**Clinical Context and Therapy Purpose**

The purpose of nonpharmacologic treatments is to provide a treatment option in patients who have rosacea and do not want to use or are unresponsive to pharmacologic therapies.

The question addressed in this evidence review is: Does the use of nonpharmacologic treatments improve the net health outcome in individuals with rosacea compared with pharmacologic treatments?

The following PICOs were used to select literature to inform this review.

**Patients**

The relevant population of interest are individuals with rosacea.

**Interventions**

Nonpharmacologic treatment options include laser and light therapy, dermabrasion, chemical peels, surgical debulking, and electrosurgery. During laser and light therapy, light energy is absorbed by hemoglobin in cutaneous vessels, which leads to vessel heating and coagulation. Lasers vary from low-powered electrical devices and vascular light lasers (for telangiectasias removal) to CO₂ lasers and intense pulsed lights that generate multiple wavelengths to treat a broader spectrum of tissue.

Frequency and duration of laser and light therapy sessions vary, from once to twice per month, for several months. Because light-based techniques do not cure rosacea, periodic treatments may be necessary to maintain symptom relief.

Laser and light therapy are administered in outpatient settings.

**Comparators**

The comparators of interest are pharmacologic therapies, which include oral and topical antibiotics, isotretinoin, β-blockers, clonidine, and anti-inflammatories.

**Outcomes**

The general outcome of interest is symptom reduction, which may include a change in redness of skin color or change in erythema score or telangiectasia score. Other outcomes of interest include a reduction in pain, subject satisfaction, and improvement in the quality of life.

Outcome measures can be assessed on treatment completion. Because laser and light therapy are not curative, outcomes can be measured months after treatment to assess symptom recurrence.

**Study Selection Criteria**

Methodologically credible studies were selected using the following principles:

- To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
- In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
To assess long-term outcomes and adverse effects, single-arm studies that capture longer periods of follow-up and/or larger populations were sought. Studies with duplicative or overlapping populations were excluded.

Systematic Reviews

A Cochrane systematic review by van Zuuren et al (2015) 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 four 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 considered low-quality and 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. Wat et al (2014) 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 a case report. A systematic review by Erceg et al (2013) assessed pulsed dye laser (PDL) and identified 2 uncontrolled studies on PDL for the treatment of rosacea. None of the systematic reviews pooled study findings on the 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 evaluating nonpharmacologic treatment for rosacea, as well as a small nonrandomized comparative study, all of which used split-faced designs, were identified. Most compared two types of lasers, and none used a placebo control or a pharmacologic treatment as a comparator. No RCTs evaluating demabrasion, chemical peels, surgical debulking, or electrosurgery for treating rosacea were identified. Representative RCTs are described briefly next.

A double-blind, randomized study by Alam et al (2013) studied 16 patients with erythematotelangiectatic rosacea. Participants received PDL treatment on a randomly selected side of the face and neodymium-yttrium aluminum garnet laser treatment on the other side. Treatments occurred at monthly intervals for four months. Fourteen (88%) of the 16 patients completed the trial 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 the redness of 8.9% after PDL and a mean difference of 2.5% after the neodymium-yttrium aluminum garnet 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 the neodymium-yttrium aluminum garnet (mean pain level, 3.1/10; p=0.003).

Maxwell et al (2010) reported on 14 patients who had acne rosacea. The study evaluated the combination of laser treatment and 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. Treatments occurred at monthly intervals for four months. Fourteen (79%) of 16 patients completed the study. At the end of treatment, blinded evaluators correctly identified the treated side of the face 47% of the time (i.e., close to the 50% expected by chance). This small study had a limited collection of objective efficacy data.

A randomized, split-face design study by Neuhaus et al (2009) included patients with moderate erythematotelangiectatic rosacea without active inflammatory papules and pustules. Twenty-nine patients were randomized to PDL on one side of the face and IPL on the other side, and four patients each received either PDL or IPL on one side of the face and no treatment on the other. Laterality of treatment (right vs left side) was also randomized. Patients underwent three treatment sessions, four weeks apart, and received their final evaluation four 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. 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 four patients each, and therefore these findings should be considered preliminary.

**Summary of Evidence**

For individuals who have rosacea who receive nonpharmacologic treatment (e.g., laser therapy, light therapy, dermabrasion), the evidence includes several small randomized, split-face design trials. The relevant outcomes are symptoms, change in disease status, and treatment-related morbidity. The RCTs evaluated laser and light therapy. No trials assessing other nonpharmacologic treatments were identified. None of the RCTs 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 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**

The American Acne and Rosacea Society (2014) issued consensus recommendations on the management of rosacea. The Society stated that lasers and intense pulsed light (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.

The American Acne and Rosacea Society (2019) issued updated consensus recommendations on the management of rosacea. 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 1:

**Table 1. 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(^a)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Persistent central facial erythema without PP lesions</td>
<td>IPL, KTP crystal laser, or pulsed-dye laser</td>
<td>B</td>
</tr>
<tr>
<td>Diffuse central facial erythema with PP lesions</td>
<td>“While the data on the use of IPL, KTP or pulsed-dye laser are limited for PP 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, KTP: Potassium titanyl phosphate; PP: papulopustular; YAG: yttrium aluminum garnet; NR: not reported.

\(^a\) 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
The AAD (2017) released online guidance for the 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
The Rosacea Consensus panel (2017), comprised of international experts including representatives from the U.S., published recommendations for rosacea treatment. The panel agreed that treatments should be based on phenotype. IPL and pulsed dye laser were recommended for persistent erythema, but not for transient erythema. IPL 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 Institutes for Health and Care Excellence
The National Institutes for Health and Care Excellence (2017) 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.

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

Medicare National Coverage
There is no national coverage determination. In the absence of a national coverage determination, coverage decisions are left to the discretion of local Medicare carriers.

Ongoing and Unpublished Clinical Trials
Some currently ongoing and unpublished trials that might influence this review are listed in Table 2.

Table 2. Summary of Key Trials

<table>
<thead>
<tr>
<th>NCTNo.</th>
<th>Trial Name</th>
<th>Planned Enrollment</th>
<th>Completion Date</th>
</tr>
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<tbody>
<tr>
<td>Ongoing</td>
<td></td>
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<td></td>
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<tr>
<td>NCT03211585a</td>
<td>Evaluation Of The Effect Of The Perfecta V-Beam Laser On Rosacea (Facial Redness, Telangiectasias And Photodamage)</td>
<td>20</td>
<td>Dec 2018 (ongoing)</td>
</tr>
<tr>
<td>NCT02075671a</td>
<td>Photodynamic Therapy for Papulopustular Rosacea</td>
<td>30</td>
<td>Feb 2019 (ongoing)</td>
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<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.
References


Documentation for Clinical Review

- No records required

Coding

This Policy relates only to the services or supplies described herein. Benefits may vary according to product design; therefore, contract language should be reviewed before applying the terms of the Policy. Inclusion or exclusion of codes does not constitute or imply member coverage or provider reimbursement.

IE

The following services may be considered investigational.
<table>
<thead>
<tr>
<th>Type</th>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>CPT®</td>
<td>15780</td>
<td>Dermabrasion; total face (e.g., for acne scarring, fine wrinkling, rhytids, general keratosis)</td>
</tr>
<tr>
<td>CPT®</td>
<td>15781</td>
<td>Dermabrasion; segmental, face</td>
</tr>
<tr>
<td>CPT®</td>
<td>15782</td>
<td>Dermabrasion; regional, other than face</td>
</tr>
<tr>
<td>CPT®</td>
<td>15783</td>
<td>Dermabrasion; superficial, any site (e.g., tattoo removal)</td>
</tr>
<tr>
<td>CPT®</td>
<td>15788</td>
<td>Chemical peel, facial; epidermal</td>
</tr>
<tr>
<td>CPT®</td>
<td>15789</td>
<td>Chemical peel, facial; demal</td>
</tr>
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<tr>
<td>CPT®</td>
<td>17108</td>
<td>Destruction of cutaneous vascular proliferative lesions (e.g., laser technique); over 50.0 sq cm</td>
</tr>
<tr>
<td>CPT®</td>
<td>17110</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; up to 14 lesions</td>
</tr>
<tr>
<td>CPT®</td>
<td>17111</td>
<td>Destruction (e.g., laser surgery, electrosurgery, cryosurgery, chemosurgery, surgical curettage), of benign lesions other than skin tags or cutaneous vascular proliferative lesions; 15 or more lesions</td>
</tr>
<tr>
<td>HCPCS</td>
<td>17340</td>
<td>Cryotherapy (CO2 slush, liquid N2) for acne</td>
</tr>
<tr>
<td>HCPCS</td>
<td>17360</td>
<td>Chemical exfoliation for acne (e.g., acne paste, acid)</td>
</tr>
<tr>
<td>HCPCS</td>
<td>30117</td>
<td>Excision or destruction (e.g., laser), intranasal lesion; internal approach</td>
</tr>
<tr>
<td>HCPCS</td>
<td>30118</td>
<td>Excision or destruction (e.g., laser), intranasal lesion; external approach (lateral rhinotomy)</td>
</tr>
<tr>
<td>HCPCS</td>
<td>30120</td>
<td>Excision or surgical planing of skin of nose for rhinophyma</td>
</tr>
<tr>
<td>HCPCS</td>
<td>E0691</td>
<td>Ultraviolet light therapy system, includes bulbs/lamps, timer and eye protection; treatment area 2 sq ft or less</td>
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<td>HCPCS</td>
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</tbody>
</table>

**Policy History**

This section provides a chronological history of the activities, updates and changes that have occurred with this Medical Policy.

<table>
<thead>
<tr>
<th>Effective Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>10/15/2007</td>
<td>New Policy Adoption</td>
</tr>
<tr>
<td>10/28/2009</td>
<td>Coding Update</td>
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<tr>
<td>04/02/2010</td>
<td>Coding Update</td>
</tr>
<tr>
<td>07/01/2011</td>
<td>Policy revision without position change</td>
</tr>
<tr>
<td>06/30/2015</td>
<td>Coding update</td>
</tr>
<tr>
<td>10/30/2015</td>
<td>Policy title change from Non-Pharmacologic Treatment of Rosacea</td>
</tr>
<tr>
<td></td>
<td>Policy revision without position change</td>
</tr>
</tbody>
</table>
## Definitions of Decision Determinations

**Medically Necessary:** Services that are Medically Necessary include only those which have been established as safe and effective, are furnished under generally accepted professional standards to treat illness, injury or medical condition, and which, as determined by Blue Shield, are: (a) consistent with Blue Shield medical policy; (b) consistent with the symptoms or diagnosis; (c) not furnished primarily for the convenience of the patient, the attending Physician or other provider; (d) furnished at the most appropriate level which can be provided safely and effectively to the patient; and (e) not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of the Member's illness, injury, or disease.

**Investigational/Experimental:** A treatment, procedure, or drug is investigational when it has not been recognized as safe and effective for use in treating the particular condition in accordance with generally accepted professional medical standards. This includes services where approval by the federal or state governmental is required prior to use, but has not yet been granted.

**Split Evaluation:** Blue Shield of California/Blue Shield of California Life & Health Insurance Company (Blue Shield) policy review can result in a split evaluation, where a treatment, procedure, or drug will be considered to be investigational for certain indications or conditions, but will be deemed safe and effective for other indications or conditions, and therefore potentially medically necessary in those instances.

## Prior Authorization Requirements (as applicable to your plan)

Within five days before the actual date of service, the provider must confirm with Blue Shield that the member's health plan coverage is still in effect. Blue Shield reserves the right to revoke an authorization prior to services being rendered based on cancellation of the member's eligibility. Final determination of benefits will be made after review of the claim for limitations or exclusions.

Questions regarding the applicability of this policy should be directed to the Prior Authorization Department at (800) 541-6652, or the Transplant Case Management Department at (800) 637-2066 ext. 3507708 or visit the provider portal at www.blueshieldca.com/provider.

Disclaimer: This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. Blue Shield of California may consider published peer-reviewed scientific literature, national guidelines, and local standards of practice in developing its medical policy. Federal and state law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over medical policy and must be considered first in determining covered services. Member contracts may differ in their benefits. Blue Shield reserves the right to review and update policies as appropriate.