

## FEP 2.01.71 Nonpharmacologic Treatment of Rosacea

**Effective Date:** April 15, 2018

**Related Policies:**

2.01.47 Targeted Phototherapy for Psoriasis  
2.01.86 Light Therapy for Vitiligo  
8.01.16 Chemical Peels

## Nonpharmacologic Treatment of Rosacea

### 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.

### FDA 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, 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).

FDA product code: GEX.

### POLICY STATEMENT

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

### BENEFIT APPLICATION

State or federal mandates (eg, Federal Employee Program) 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 by their medical necessity.

Plans may want to examine specific contract language regarding the definitions of cosmetic services to determine whether contract or benefit exclusions may apply to the treatment of rosacea.

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### RATIONALE

#### 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 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 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.

### SUPPLEMENTAL INFORMATION

#### 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.<sup>9</sup> The Society stated that lasers and intensely pulsed light 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.

##### American Academy of Dermatology

In 2017, the American Academy of Dermatology (AAD) released online guidance for treatment and management of rosacea.<sup>10</sup> AAD encouraged patients to identify their triggers to minimize symptoms, including protection from exposure to the sun, heat, stress, alcohol, and spicy foods. AAD indicated that “laser or light therapy may be considered to reduce visible blood vessels. Thickening of the skin associated with may be treated with laser skin resurfacing.” 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.”

##### National Institutes for Health and Care Excellence

In 2017, National Institutes for Health and Care Excellence published online pathways addressing skin damage and skin conditions.<sup>11</sup> 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 (NCD). In the absence of an NCD, coverage decisions are left to the discretion of local Medicare carriers.

### REFERENCES

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10. American Academy of Dermatology. Lasers and lights: How well do they treat rosacea? 2017; <https://www.aad.org/public/diseases/acne-and-rosacea/rosacea/lasers-and-lights-how-well-do-they-treat-rosacea> Accessed October 23, 2017.
11. National Institutes for Health and Care Excellence (NICE). Skin conditions overview. 2017; <https://pathways.nice.org.uk/pathways/skin-conditions>. Accessed October 30, 2017.

### POLICY HISTORY

Date	Action	Description
December 2011	New Policy	
March 2013	Update Policy	Policy updated with literature review through September, references updated, statement changed to Not Medically Necessary.
March 2014	Update Policy	Policy updated with literature review, adding references 2, 3, 6, and 11. Literature review reorganized. No change to policy statement.
March 2015	Update Policy	Policy updated with literature review, adding references 2 and 8, removing others. There are no changes to the policy statement.
June 2016	Update Policy	Policy updated with literature review through November 10, 2015; reference 1 added. Policy statement unchanged.
March 2017	Update Policy	Policy updated with literature review; reference 9 added. Policy statement unchanged.
March 2018	Update Policy	Policy updated with literature review through October 30, 2017; references 10-11 added. Policy statement unchanged except not medically necessary corrected to investigational due to 510k FDA status of devices.

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