BlueCross BlueShield of Alabama

Name of Blue Advantage Policy:

Nonpharmacologic Treatment of Rosacea

Policy #: 166
Category: Surgery

Latest Review Date: January 2021
Policy Grade: C

BACKGROUND:

Blue Advantage *medical policy does not conflict with Local Coverage Determinations (LCDs), Local Medical Review Policies (LMRPs) or National Coverage Determinations (NCDs) or with coverage provisions in Medicare manuals, instructions or operational policy letters. In order to be covered by Blue Advantage the service shall be reasonable and necessary under Title XVIII of the Social Security Act, Section 1862(a)(1)(A). The service is considered reasonable and necessary if it is determined that the service is:*

1. *Safe and effective;*
2. *Not experimental or investigational*;*
3. *Appropriate, including duration and frequency that is considered appropriate for the service, in terms of whether it is:*
   - *Furnished in accordance with accepted standards of medical practice for the diagnosis or treatment of the patient's condition or to improve the function of a malformed body member;*
   - *Furnished in a setting appropriate to the patient's medical needs and condition;*
   - *Ordered and furnished by qualified personnel;*
   - *One that meets, but does not exceed, the patient's medical need; and*
   - *At least as beneficial as an existing and available medically appropriate alternative.*

In accordance with Title XVIII of the Social Security Act, Section 1862 (a)(10) cosmetic surgery or expenses incurred in connection with such surgery is not covered except as required for the prompt repair of accidental injury or for improvement of the functioning of a malformed body member.

Routine costs of qualifying clinical trial services with dates of service on or after September 19, 2000 which meet the requirements of the Clinical Trials NCD are considered reasonable and necessary by Medicare. Providers should bill* ***Original Medicare* *for covered services that are related to* ***clinical trials*** *that meet Medicare requirements (Refer to Medicare National Coverage Determinations Manual, Chapter 1, Section 310 and Medicare Claims Processing Manual Chapter 32, Sections 69.0-69.11).*

POLICY:

Blue Advantage will treat **laser/light therapy for the treatment of rosacea-associated telangiectasias** as a **covered** benefit when **ALL** of the following criteria are met:

- Must have clinical documentation of diagnosis of at least Subtype II (which is characterized by persistent central facial flushing, transient papules and/or pustules and telangiectasias). These telangiectasias must be coarse versus fine or a 3 out of 0-3. The primary feature should be ranked as severe telangiectasias per the Primary Features by the National Rosacea Society Clinical Scorecard.
- There must be clinical documentation of prior treatment, such as but not limited to metronidazole, and response to each treatment, to include the length of time treatment was used.
- Photos must document the presence of the disorder and be submitted for review along with the clinical documentation as listed above.

Blue Advantage will treat **laser/light therapy or surgical planing of rosacea associated rhinophyma** as a **covered** benefit when **ALL** of the following criteria are met:

- Must have diagnosis of **advanced** rosacea
- Documentation of treatment, such as but not limited to metronidazole, and response to treatments
- Photographs must document presence of disorder

Blue Advantage does not approve or deny procedures, services, testing, or equipment for our members. Our decisions concern coverage only. The decision of whether or not to have a certain test, treatment or procedure is one made between the physician and his/her patient. Blue Advantage administers benefits based on the members' contract and medical policies. Physicians should always exercise their best medical judgment in providing the care they feel is most appropriate for their patients. Needed care should not be delayed or refused because of a coverage determination.

DESCRIPTION OF PROCEDURE OR SERVICE:

Rosacea is a chronic, inflammatory skin condition that cannot be cured; 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.

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. Since 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, it 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 (i.e., erythema, papules, pustules, telangiectasias) 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 sufficient to warrant the preventive removal of rhinophymatous tissue.

Wilkin, et al, in 2002 published in the Journal of the American Academy of Dermatology the standard classification of rosacea. This classification includes four subtypes:

Subtype 1: Erythematotelangiectatic rosacea- characterized by flushing and persistent central facial erythema with or without telangiectasia.

Subtype 2: Papulopustular rosacea- characterized by persistent central facial erythema with transient, central facial papules, pustules or both, this subtype may be seen after or in combination with subtype 1, including the presence of telangiectases.

Subtype 3: Phymatous rosacea- characterized by thickening skin, irregular surface nodularities and enlargement that may occur on the nose, chin, forehead, cheeks or ears. May also be seen after or in combination with subtypes 1 or 2.

Subtype 4: Ocular rosacea- characterized by foreign body sensation in the eye, burning or stinging, dryness, itching, ocular photosensitivity, blurred vision, telangiectasia of the sclera or other parts of the eye, or periorbital edema. May also be seen with cutaneous signs and symptoms of rosacea.

Granulomatous rosacea ischaracterized by non-inflammatory; hard; brown, yellow, or red cutaneous papules; or nodules of uniform size and may occur in locations other than those in which the phymas are observed. Each subtype includes the fewest signs sufficient to make a diagnosis of the subtype.

Wilkin, et al, also authored a report supported by the National Rosacea Society in 2004 to develop a standard grading system for rosacea. Primary signs and symptoms may be graded as absent, mild, moderate, or severe (0-3) and most secondary features may be graded as absent or present. Nasal and malar telangiectases should be identified independently, and be qualitatively described as fine and threadlike to coarse.

A Rosacea Clinical Scorecard has been developed by the National Rosacea Society and may be accessed or viewed at www.rosacea.org.

Treatment
Rosacea treatment can be effective in relieving signs and symptoms. Treatment may include oral and topical antibiotics, isotretinoin, ß-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.

Treatment is encouraged early following diagnosis. Avoidance of trigger factors is the initial therapeutic step. Oral antibiotics, such as tetracycline, doxycycline (Vibramycin), and metronidazole (Flagyl) are used to treat the papulopustular rosacea. Topical metronidazole (MetroCream or MetroGel) is also effective, however some patients complain of burning and stinging. Topical clindamycin may be used as an alternative. Oral tetracycline and doxycycline have been shown to effectively control the ocular symptoms of rosacea.

Second-line therapy may be necessary when antibiotics are not completely successful such as oral isotretinoin (Accutane) or topical tretinoin (Retin-A). Other items used as second-line may be trimethoprim-sulfamethoxazole (Bactrim, Septra) methotrexate, dapsone, primaquine, chloroquine (Aralen) and oral prednisone.

Treatment of telangiectasias is one of the most difficult problems associated with rosacea. Use of a pulsed dye laser (PDL) may be effective in advanced cases. Facial telangiectasis is also amenable to pulsed light sources. The pulsed dye laser was initially developed to treat port-wine stains and has also become the treatment of choice for many acquired vascular lesions including telangiectasias. Pulses must not be overlapped by more than 10% to reduce the risk of scarring and textural changes. PhotoDerm® VL is an intense pulsed light source that emits light at variable pulse durations, intervals and wavelengths. PhotoDerm® PL also is a non-invasive medical system that uses light therapy for skin treatment. The VersaPulse laser provides four different wavelengths in a single machine and can be used to treat facial telangiectasias and port-wine stains. Rothfleisch et al reported in an article of a study by Lowe et al that 24 of 27 patients had good to excellent results of reduction of telangiectasia, erythema and overall appearance with one to three treatments with the PDL. Papules and pustules were decreased in 59% of the patients and no side effects. Many of the patients with clinical improvement were also able to reduce the dosage of topical or systemic antibiotic therapy. Jasim et al reported on 12 patients with rosacea-associated telangiectasia and received pulsed dye laser treatment. After one treatment nine of 12 patients had at least 25% improvement in their rosacea-associated telangiectasia.

The American Academy of Dermatology in their Academy Guidelines of Care for Laser Surgery lists facial and truncal telangiectases with a source of rosacea to be responsive to continuous and quasi-continuous-wave laser treatment and to pulsed lasers and pulsed light sources. Pulsed and scanned CO2 lasers are effective for rhinophyma as well.

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.

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. The relevant outcomes are symptoms, change in disease status, and treatmentrelated 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.

KEY POINTS:

This policy has been updated regularly with searches of the MEDLINE database. The most recent literature review was performed through October 21, 2020.

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. They stated that lasers and intense pulsed light (IPL) devices can improve certain clinical manifestations of rosacea that have not responded to medical therapy. The recommendations indicated that these therapies will need 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

Condition	Recommendation	Grade[a]
Persistent central facial erythema without papulopustular lesions	IPL, potassium titanyl crystal laser, or pulsed-dye laser	B

Diffuse central facial erythema with papulopustular lesions	"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"	NR
Granulomatous rosacea	Intense pulsed-dye laser "No current standard of treatment; limited data based on case reports"	C
Phymatous Rosacea	"Surgical therapy for fully developed phymatous changed (carbon dioxide laser, erbium-doped [YAG] laser, electrosurgery, dermabrasion)" "Treatment selection dependent on stage of development (early or fibrotic) and extent of inflammation (active or burnt out)"	C

IPL: intense pulsed light, YAG: yttrium aluminium 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 (AAD)
The AAD (2017) released online guidance for the treatment and management of rosacea. 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 United States, 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. 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 Institutes for Health and Care Excellence
In 2017, 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.

Us Preventive Services Task Force Recommendations
Not applicable.

KEY WORDS:
Rosacea, telangiectasis, telangiectasias, rhinophyma, pulse dye laser, PhotoDerm, pulsed light source, intense pulse light source, VersaPulse, Candela®, Lumenis®, Harmony® XL, UV-300 Pulsed Light Therapy System, CoolTouch PRIMA Pulsed Light Therapy System

APPROVED BY GOVERNING BODIES:
Several laser and light therapy systems have been cleared for marketing by FDA through the 501(k) process for a variety of dermatologic indications, including rosacea. For example, rosacea is among the indications for:

- Vbeam laser system (Candela);
- Stellar M22™ laser system (Lumenis);
- excel VT®, excel V®, and xeo® laser systems (Cutera);
- Harmony® XL multiapplication platform laser device (Alma Lasers, Israel);
- UV-300 Pulsed Light Therapy System (New Star Lasers);
- CoolTouch® PRIMA Pulsed Light Therapy System (New Star Lasers).

BENEFIT APPLICATION:
Coverage is subject to member's specific benefits. Group specific policy will supersede this policy when applicable.

CODING:
CPT code:

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
30120	Excision or surgical planing of skin of nose for rhinophyma

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POLICY HISTORY:

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Medical Policy Group, January 2019
Medical Policy Group, December 2019
Medical Policy Group, January 2021

This medical policy is not an authorization, certification, explanation of benefits, or a contract. Eligibility and benefits are determined on a case-by-case basis according to the terms of the member's plan in effect as of the date services are rendered. All medical policies are based on (i) research of current medical literature and (ii) review of common medical practices in the treatment and diagnosis of disease as of the date hereof. Physicians and other providers are solely responsible for all aspects of medical care and treatment, including the type, quality, and levels of care and treatment.

This policy is intended to be used for adjudication of claims (including pre-admission certification, pre-determinations, and pre-procedure review) in Blue Cross and Blue Shield's administration of plan contracts.