Name of Policy: Rosacea Treatment

Policy #: 166              Latest Review Date: January 2014
Category: Surgery          Policy Grade: C

Background/Definitions:
As a general rule, benefits are payable under Blue Cross and Blue Shield of Alabama health plans only in cases of medical necessity and only if services or supplies are not investigational, provided the customer group contracts have such coverage.

The following Association Technology Evaluation Criteria must be met for a service/supply to be considered for coverage:

1. The technology must have final approval from the appropriate government regulatory bodies;
2. The scientific evidence must permit conclusions concerning the effect of the technology on health outcomes;
3. The technology must improve the net health outcome;
4. The technology must be as beneficial as any established alternatives;
5. The improvement must be attainable outside the investigational setting.

Medical Necessity means that health care services (e.g., procedures, treatments, supplies, devices, equipment, facilities or drugs) that a physician, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury or disease or its symptoms, and that are:

1. In accordance with generally accepted standards of medical practice; and
2. Clinically appropriate in terms of type, frequency, extent, site and duration and considered effective for the patient’s illness, injury or disease; and
3. Not primarily for the convenience of the patient, physician or other health care provider; and
4. 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 that patient’s illness, injury or disease.
Description of Procedure or Service:
Rosacea is a chronic, inflammatory skin condition that cannot be cured; the goal of treatment is symptom management. 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, 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) that can 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 sufficiently great to warrant preventive removal of rhinophymatous tissue.

While rosacea cannot be eliminated, treatment can be effective to relieve its signs and symptoms. Treatment may include oral and topical antibiotics, isotretinoin, beta-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. 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. Nonpharmacologic therapy has also been tried in patients who cannot tolerate or do not want to use pharmacologic treatments. The 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.

The National Rosacea Society Expert Committee on the Classification and Staging of Rosacea has developed a standard classification system that divides the disease into four distinct subtypes: erythematotelangiectactic rosacea; papulopustular rosacea; phymatous rosacea; and ocular rosacea.
**Policy:**

*Laser/light therapy for the treatment of rosacea-associated telangiectasias meets* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage 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.

*Laser/light therapy or surgical planing of rosacea associated rhinophyma meets* Blue Cross and Blue Shield of Alabama’s medical criteria for coverage 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 Cross and Blue Shield of Alabama 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 Cross and Blue Shield of Alabama administers benefits based on the members' contract and corporate 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.*

**Key Points:**

Rosacea is a common skin condition of uncertain etiology that can lead to significant facial disfigurement, ocular complications, and severe emotional distress. It affects about 13 million people in the United States. Rosacea is most often seen after the age of 30 and affects women three times more than men. Northern European or Celtic descent with fair-skin are most commonly affected. Rosacea is also associated with sun-damaged skin.

Rosacea is associated with an inflammatory process about which very little is known. Manifestations vary from patient to patient and the predominant presenting symptoms are intermittent, central facial flushing and erythema. Progression of symptoms in the early stages includes central facial erythema and telangiectasis. Chronic inflammatory infiltrate with central facial papules and possibly sterile pustules may follow. The later stage of rosacea may progress
Rosacea is a chronic, relapsing disorder, and long-term treatment is generally required.

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. 2002 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.

**May 2008 Update**
No new published peer-reviewed literature was identified that would alter the coverage statement of this policy.

**February 2009 Update**
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

Variants
Granulomatous rosacea- characterized by non-inflammatory; hard; brown, yellow, or red cutaneous papules; or nodules of uniform size. The granulomatous rosacea 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.

January 2010
One comparative study on a non-pharmacologic treatment for rosacea was identified, a small randomized controlled trial. Neuhaus and colleagues included patients with moderate erythematotelangiectatic rosacea without active inflammatory papules and pustules who were at least 18 years old and had not received previous treatment with a laser or light-based device, were not undergoing treatment with a photosensitizing agent and had not had changes to their medication in the past three months. The study used a split-face design; 29 patients were randomly assigned to receive treatment with a pulsed dye laser (PDL, Vbeam, Candela Corp) on one side of the face and an intense pulsed light (IPL, Quantum, Lumenis) 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 versus left side) was also randomly assigned. Patients underwent a total of 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 pulsed dye laser and intense pulsed light groups. Thus, we cannot conclude that one of these treatments is superior to the other. To determine whether both are effective or
ineffective, studies with a control group are needed. In this study, there were significantly lower erythema and telangiectasia scores for both IPL and PDL treatment compared to control (p<0.01). However, the comparisons with no treatment included only four patients each and therefore these findings should be considered preliminary.

A search of ClinicalTrials.gov identified one active trial evaluating a non-pharmacologic treatment for rosacea. This is a single-blind, non-comparative study of combination therapy with calcium dobesilate and a pulsed dye laser and is currently recruiting patients. The final data collection date for the primary outcome measure is June 2010.

**December 2010 Update**

In 2010, Maxwell and colleagues published a split-face design study that included 14 patients with acne rosacea. The study evaluated the combination of laser treatment and a topical treatment. All patients received six sessions of treatment with a 532 laser and a retinaldehyde-based topical application over three months on a randomly selected side of the face. The other side of the face served as the control. Eleven out of 14 patients (79%) completed the study. At the end of the treatment period, 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 was a small study with drop-outs and involved limited collection of objective efficacy data.

**2012 Update**

In 2011, van Zuuren and colleagues published a Cochrane systematic review on interventions for rosacea (an update of a 2005 review). The systematic review identified 58 randomized controlled trials (RCTs) that compared treatments to placebo or a different intervention in adults with clinically diagnosed moderate to severe rosacea. The investigators identified only one trial on light therapy and one trial on laser therapy, and the trials did not compare these interventions with pharmacologic treatments or placebo controls. The remainder of the RCTs evaluated pharmacologic treatments. The Cochrane review highlights the lack of evidence on light and laser therapy for treating rosacea, especially in comparison to nonpharmacologic treatments. In addition, as the authors noted, additional trials evaluating nonpharmacologic therapies should be a priority because they have the potential to treat symptoms on the face, which is highly desirable.

The literature on nonpharmacologic treatment of rosacea primarily consists of case series. One of the largest series was published in 2011 by Kassir and colleagues who reviewed the medical records from 102 patients with mild to severe rosacea. All patients had their entire face treated with an intense pulsed light (IPL) system; the number of treatments and treatment parameters were individualized. Patients were evaluated pre-treatment and one to two weeks post-treatment. According to clinician assessment and photodocumentation, 80% of patients had reduced redness after treatment. Photodocumentation showed a 51% reduction in telangiectasias. The study did not include long-term follow-up. Another of the larger series was published in 2005 by Schroeter and colleagues in the Netherlands. The authors reported 77.8% long-term clearance (follow-up of 12–99 months) of telangiectasia in 60 randomly selected patients with facial rosacea who had been treated with IPL.
2013 Update
Nonpharmacologic Treatments of Rosacea

Systematic reviews
A 2013 systematic review addressed literature published through August 2011 on pulsed dye laser treatment for a variety of inflammatory skin diseases. The authors identified 52 articles on RCTs, observational studies and case series. Most studies addressed pulsed dye laser (PDL) treatment of psoriasis, acne vulgaris and lupus. There were only two articles on pulsed dye laser treatment of rosacea, and neither of these included a control or comparison group. Both studies were on papulopustular rosacea.

Randomized controlled trials:
No RCTs evaluating dermabrasion, chemical peels, surgical debulking or electrosurgery for treating rosacea were identified. Representative RCTs are described briefly below.

A 2013 double-blind study by Alam and colleagues studied 16 patients with erythematotelangiectatic rosacea. Participants received pulsed dye laser (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 four months. Fourteen of the 16 patients (88%) 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 post-treatment. 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 of 3.9 out of 10) compared to Nd:YAG (mean pain level: 3.1), p=0.003.

Practice Guidelines and Position Statements
No practice guidelines or position statements from national organizations on the use of nonpharmacologic treatments for treating rosacea were identified.

Key Words:
Rosacea, telangiectasis, telangiectasias, rhinophyma, pulse dye laser, PhotoDerm, pulsed light source, intense pulse light source, VersaPulse

Approved by Governing Bodies:
Not applicable

Benefit Application:
Coverage is subject to member’s specific benefits. Group specific policy will supersede this policy when applicable.

ITS: Home Policy provisions apply
FEP contracts: Special benefit consideration may apply. Refer to member’s benefit plan. FEP does not consider investigational if FDA approved and will be reviewed for medical necessity.
Coding:
CPT code: 17106  Destruction of cutaneous vascular proliferative lesions (eg, laser technique); less than 10 sq cm
17107  Destruction of cutaneous vascular proliferative lesions (eg, laser technique); 10.0 to 50.0 sq cm
17108  Destruction of cutaneous vascular proliferative lesions (eg, laser technique); over 50.0 sq cm
30120  Excision or surgical planing of skin of nose for rhinophyma

References:

**Policy History:**
Medical Policy Group, August 2004 (1)
Medical Policy Administration Committee, August 2004
Available for comment August 11-September 24, 2004
Medical Policy Group, May 2006 (1)
Medical Policy Group, May 2008 (1)
Medical Policy Group, February 2009 (1)
Medical Policy Administration Committee, March 2009
Available for comment February 10-March 26, 2009
Medical Policy Group, January 2010 (1)
Medical Policy Group, December 2010 (1): Key Points and reference list updated
Medical Policy Panel, December 2012
Medical Policy Group, May 2013(3): 2012 Updates to Description, Key Points and References; no change in policy statement
Medical Policy Panel, December 2013
Medical Policy Group, January 2014(3): 2013 Updates to Key Points and References; no change in policy statement

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.