MEDICAL POLICY

POLICY TITLE	**ROSACEA**
POLICY NUMBER	**MP-2.071**

Original Issue Date (Created):	**August 8, 2003**
Most Recent Review Date (Revised):	**March 25, 2014**
Effective Date:	**June 1, 2014**

I. POLICY

Pharmacologic treatment (e.g., topical and oral medication) may be considered **medically necessary** to control the symptoms and signs of rosacea.

Surgical treatment of severe disfigurement **associated with rhinophyma** including lasers, dermabrasion or electrosurgery may be considered **medically necessary** to sculpt the nose to a normal shape and appearance.

Nonpharmacologic treatment of rosacea, including but not limited to, laser and light therapy, dermabrasion, chemical peels, surgical debulking and electrosurgery is considered **investigational**. There is insufficient evidence to support a conclusion concerning the health outcomes or benefits associated with this procedure.

Cross-reference:
MP-1.004 Cosmetic and Reconstructive Surgery

II. PRODUCT VARIATIONS

TOP

[N] = No product variation, policy applies as stated
[Y] = Standard product coverage varies from application of this policy, see below

- [N] Capital Cares 4 Kids
- [N] PPO
- [N] HMO
- [Y] SeniorBlue HMO**
- [Y] SeniorBlue PPO**
- [N] Indemnity
- [N] SpecialCare
- [N] POS
- [Y] FEP PPO*

POLICY TITLE	ROSACEA
POLICY NUMBER	MP-2.071

* Refer to FEP Medical Policy Manual MP-2.01.71 Nonpharmacologic Treatment of Rosacea. The FEP Medical Policy Manual can be found at: www.fepblue.org

**Medicare may cover treatment of rosacea using FDA-approved laser procedures (see Centers for Medicare and Medicaid Services (CMS) National Coverage Determinations 140.5, Laser Procedures. Medicare may also cover treatment of rosacea (see Novitas Solutions Local Coverage Determination (LCD) L27527, Removal of Benign or Premalignant Skin Lesions).

III. DESCRIPTION/BACKGROUND

TOP

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 treatments.

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 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.

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 a variety of dermatologic indications, including rosacea. For example, rosacea is among the indications for the Candela pulse dye laser system (Candela Corp.; Wayland, MA), the Lumenis One Family of Systems intense pulsed light component (Lumenis Inc.; Santa Clara, Ca), and the Harmony XL multi-application platform laser device (Alma Lasers; Israel).

IV. RATIONALE

TOP

This policy is updated regularly with searches of the MEDLINE database. The most recent literature search was performed for the period October 2012 through October 25, 2013. Following is a summary of the key literature to date.

Nonpharmacologic Treatments of Rosacea

Systematic reviews. In 2011, van Zuuren et al published a Cochrane systematic review on interventions for rosacea.(1) 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 1 trial on light therapy and 1 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. 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.

A 2013 systematic review addressed literature published through August 2011 on pulsed dye laser (PDL) treatment for a variety of inflammatory skin diseases.(2) The authors identified 52 articles on RCTs, observational studies and case series. Most studies addressed PDL treatment of psoriasis, acne vulgaris and lupus. There were only 2 articles on PDL treatment of rosacea, and neither of these included a control or comparison group. Both studies were on papulopustular rosacea.

Randomized controlled trials. Several randomized trials on nonpharmacologic treatment for rosacea, as well as a small nonrandomized comparative study, all of which used split-faced designs, were identified.(3-6) All but one compared 2 types of lasers, and the remaining study had

a no-treatment comparison group. None of the studies used a placebo control or used a pharmacologic treatment as the comparison intervention; these are preferred comparators for evaluating the efficacy of nonpharmacologic treatments. 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 et al studied 16 patients with erythematotelangiectatic rosacea.(3) Participants received 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 4 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, 3.9/10) compared to Nd:YAG (mean pain level, 3.1/10; p=0.003).

In 2010, Maxwell et al reported on 14 patients who had acne rosacea.(4) The study evaluated the combination of laser treatment and a 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. Eleven 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 (ie, close to the 50% expected by chance). This was a small study with drop-outs and involved limited collection of objective efficacy data.

A 2009 study by Neuhaus et al included patients with moderate erythematotelangiectatic rosacea without active inflammatory papules and pustules.(5) Twenty-nine patients were randomly assigned to receive treatment with a PDL on 1 side of the face and an intense pulsed light (IPL) on the other side, and 4 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 3 treatment sessions, 4 weeks apart and received their final evaluation 4 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. Thus, we cannot conclude that one of these treatments is superior to the other. 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 4 patients each, and therefore these findings should be considered preliminary.

Observational studies. Several case series evaluating nonpharmacologic treatment of rosacea observational studies have been published.(7-11) One of the largest series was published in 2011

by Kassir et al who reviewed the medical records from 102 patients with mild to severe rosacea.(8) All patients had their entire face treated with an IPL system; the number of treatments and treatment parameters were individualized. Patients were evaluated pretreatment and 1 to 2 weeks post-treatment. According to clinician assessment and photo documentation, 80% of patients had reduced redness after treatment. Photo documentation 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 et al in the Netherlands.(9) The authors reported 77.8% long-term clearance (follow-up, 12-99 months) of telangiectasia in 60 randomly selected patients with facial rosacea who had been treated with IPL.

Summary

The evidence to date remains insufficient to conclude that nonpharmacologic treatment for rosacea improves health outcomes. Three small randomized split-face design studies using laser therapy have been published, but these compare different methods of laser treatment or compare laser treatment to no treatment, and therefore do not offer useful evidence on the efficacy of nonpharmacologic treatment compared to alternative treatment options. Moreover, a 2013 systematic review found insufficient evidence on laser treatment for rosacea. There is a need for further RCTs comparing nonpharmacologic treatments to placebo controls and to pharmacologic treatments. Thus, nonpharmacologic treatments for rosacea are considered investigational.

Practice Guidelines and Position Statements

No guidelines or statements were identified.

V. DEFINITIONS

TOP

BASIC ACTIVITIES OF DAILY LIVING include and are limited to walking in the home, eating, bathing, dressing, and homemaking.

CONJUNCTIVITIS refers to inflammation of the mucous membrane that lines the eyelids.

BASIC ACTIVITIES OF DAILY LIVING include and are limited to walking in the home, eating, bathing, dressing, and homemaking.

CONJUNCTIVITIS refers to inflammation of the mucous membrane that lines the eyelids.

COSMETIC SURGERY refers to an elective procedure performed primarily to restore a person's appearance by surgically altering a physical characteristic that does not prohibit normal function, but is considered unpleasant or unsightly.

FUNCTIONAL IMPAIRMENT refers to a condition that describes a state where an individual is physically limited to perform basic daily activities.

HYPERPLASIA refers to excessive proliferation of normal cells in the normal tissue arrangement of an organ.

TELANGIECTIASIS refers to a vascular lesion formed by dilation of a group of small blood vessels.

VI. BENEFIT VARIATIONS

TOP

The existence of this medical policy does not mean that this service is a covered benefit under the member's contract. Benefit determinations should be based in all cases on the applicable contract language. Medical policies do not constitute a description of benefits. A member's individual or group customer benefits govern which services are covered, which are excluded, and which are subject to benefit limits and which require preauthorization. Members and providers should consult the member's benefit information or contact Capital for benefit information.

VII. DISCLAIMER

TOP

Capital's medical policies are developed to assist in administering a member's benefits, do not constitute medical advice and are subject to change. Treating providers are solely responsible for medical advice and treatment of members. Members should discuss any medical policy related to their coverage or condition with their provider and consult their benefit information to determine if the service is covered. If there is a discrepancy between this medical policy and a member's benefit information, the benefit information will govern. Capital considers the information contained in this medical policy to be proprietary and it may only be disseminated as permitted by law.

VIII. CODING INFORMATION

TOP

Note: This list of codes may not be all-inclusive, and codes are subject to change at any time. The identification of a code in this section does not denote coverage as coverage is determined by the terms of member benefit information. In addition, not all covered services are eligible for separate reimbursement.

POLICY TITLE	ROSACEA
POLICY NUMBER	MP-2.071

Covered when medically necessary as outlined in the policy above:

CPT Codes®								
15780	15781	15782	15783	17000	17003	17004	17106	17107
17108	30117	30118						

ICD-9-CM Diagnosis Code*	Description
695.3	ROSACEA

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

The following ICD-10 diagnosis codes will be effective October 1, 2015:

ICD-10-CM Diagnosis Code*	Description
L71.0-L71.9	Rosacea code range

*If applicable, please see Medicare LCD or NCD for additional covered diagnoses.

IX. REFERENCES

TOP

1. Van Zuuren EJ, Kramer S, Carter B et al. Interventions for rosacea. Cochrane Database Syst Rev 2011; (3):CD003262.

2. Erceg A, de Jong EM, van de Kerkhof PC et al. The efficacy of pulsed dye laser treatment for inflammatory skin diseases: A systematic review. J Am Acad Dermatol 2013; 69(4):609-15 e8.

3. Alam M, Voravutinon N, Warycha M et al. Comparative effectiveness of nonpurpuragenic 595-nm pulsed dye laser and microsecond 1064-nm neodymium:yttrium-aluminum-garnet laser for treatment of diffuse facial erythema: A double-blind randomized controlled trial. J Am Acad Dermatol 2013; 69(3):438-43.

4. Maxwell E, Ellis DA, Manis H. Acne rosacea: effectiveness of 532 nm laser on the cosmetic appearance of the skin. J Otolaryngol Head Neck Surg 2010; 39(3):292-6.

5. Neuhaus IM, Zane LT, Tope WD. Comparative efficacy of nonpurpuragenic pulsed dye laser and intense pulsed light for erythematotelangiectatic rosacea. Dermatol Surg 2009; 35(6):920-8.

6. Salem SA, Abdel Fattah NS, Tantawy SM et al. Neodymium-yttrium aluminum garnet laser versus pulsed dye laser in erythemato-telangiectatic rosacea: comparison of clinical efficacy and effect on cutaneous substance (P) expression. J Cosmet Dermatol 2013; 12(3):187-94.

7. Bryld LE, Jemec GB. Photodynamic therapy in a series of rosacea patients. J Eur Acad Dermatol Venereol 2007; 21(9):1199-202.

8. Kassir R, Kolluru A, Kassir M. Intense pulsed light for the treatment of rosacea and telangiectasias. J Cosmet Laser Ther 2011; 13(5):216-22.

9. Schroeter CA, Haaf-von Below S, Neumann HA. Effective treatment of rosacea using intense pulsed light systems. Dermatol Surg 2005; 31(10):1285-9.

10. Tan SR, Tope WD. Pulsed dye laser treatment of rosacea improves erythema, symptomatology, and quality of life. J Am Acad Dermatol 2004; 51(4):592-9.

11. Shim TN, Abdullah A. The effect of pulsed dye laser on the dermatology life quality index in erythematotelangiectatic rosacea patients: an assessment. J Clin Aesthet Dermatol 2013; 6(4):30-2.

Other Sources

***C**enters for Medicare and Medicaid Services (CMS) National Coverage Determination (NCD) 140.5, Laser Procedures Effective 5/1/1997. CMS [Website]: https://www.cms.gov Accessed January 21, 2014.*

***N**ovitas Solutions Services Local Coverage Determination (LCD) L27527: Removal of Benign or Premalignant Skin Lesions Effective 08/28/12. Accessed January 21, 2014*

***T**aber's Cyclopedic Medical Dictionary, 21st edition.*

X. POLICY HISTORY

TOP

MP 2.071	**CAC 6/24/03**
	CAC 12/14/04
	CAC 1/31/06
	CAC 5/30/06
	CAC 6/26/07
	CAC 11/27/07
	CAC 11/25/08
	CAC 11/24/09 Consensus
	CAC 11/30/10 Consensus

POLICY TITLE	ROSACEA
POLICY NUMBER	MP-2.071

	CAC 2/28/12 Adopt BCBSA. Laser and light therapy, dermabrasion, chemical peels, surgical debulking and electrosurgery, are considered investigational. Vascular lasers and intense pulsed light were previously considered not medically necessary. Statements related to medical treatment (e.g., topical and oral medication) and surgical treatment of severe disfigurement associated with rhinophyma remain. FEP variation revised.
	CAC 6/4/13 Consensus list review. Administrative code review.
	CAC 3/25/14 Consensus. Minor wording changes in policy statements to improve clarity did not change intent. In statement one changed "medical" to pharmacologic". In third policy statement added the word "nonpharmacologic" to specify type of treatment. References updated. Rationale section added.

Top