Rosacea, Topical Products

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Related Coverage Resources

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Overview
This policy supports medical necessity review for topical products indicated for the treatment of rosacea. * Note that Finacea cream 20% is only indicated for treatment for acne.

Coverage Policy Statement
Topical rosacea products (Finacea® 15% foam/gel, MetroCream® 0.75% cream, Metrogel® 0.75% gel, MetroLotion® 0.75% lotion, Noritate® 1% cream, Soolantra® 1% cream) are medically necessary when the following are met:

1. Criteria associated with FDA Indications
2. Criteria associated with Other Uses with Supportive Evidence
3. Specific Additional Criteria [when part of Cigna managed drug list or plan requirements]
4. Preferred Product Requirement Criteria [when part of Cigna managed drug list or plan requirements]

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Approval duration is 12 months unless otherwise stated.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

**Documentation:** When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents. Documentation may include, but is not limited to, chart notes, prescription claims records, and/or prescription receipts

Refer to each criteria section below.

### FDA Indication Criteria

None.

### Other Uses with Supportive Evidence Criteria

None.

### Specific Additional Criteria

None.

### Preferred Product Requirement Criteria

Coverage varies across plans. Refer to the customer’s benefit plan document for coverage details. Where coverage requires the use of preferred products, the following criteria apply:

Approve for an individual when there is documentation of ONE of the following:

- The individual has had inadequate efficacy OR contraindication according to FDA label OR significant intolerance to ALL of covered alternatives according to the table below OR

- The individual is not a candidate for ALL covered alternatives according to the table below due to being subject to a warning per the prescribing information (labeling), having a disease characteristic, individual clinical factor[s], or other attributes/conditions or is unable to administer and requires this dosage formulation

<table>
<thead>
<tr>
<th>Non-Covered Product</th>
<th>Standard / Performance</th>
<th>Value / Advantage</th>
<th>Cigna Total Savings</th>
<th>Legacy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Finacea 15% Foam (azelaic acid)</td>
<td>Individuals with rosacea: <strong>TWO</strong> formulary topical products from the following: azelaic acid 15% gel, sodium sulfacetamide 10%/sulfur 5%, metronidazole 0.75% or 1% (cream, gel, or lotion)</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td>Individuals with acne vulgaris: <strong>TWO</strong> formulary topical products from the following: topical antibiotic products (for example, clindamycin, erythromycin, benzoyl peroxide), topical retinoids (for example, tretinoin, adapalene, tazarotene), azelaic acid 15% gel, sulfacetamide-containing products</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
**Conditions Not Covered**

Any other exception is considered not medically necessary.

**Background**

Rosacea, a chronic, inflammatory facial skin disorder, affects approximately 16 million people in the US.\(^1-3\) The prevalence of rosacea has been estimated to range from < 1% to > 20%.\(^2\) Both cultural and social perceptions of the disease (among other factors, including study methodology and study populations) may confound the prevalence reporting; hence, the wide range in the estimate. Rosacea is more common in fair-skinned people of Northern and Eastern European descent, but it has been reported in people of other ethnicities.\(^3\) The hallmark of rosacea is central facial persistent erythema, typically affecting the cheeks, chin, forehead, and nose; the perioral and periocular regions are generally unaffected.\(^2\) Patients with rosacea typically present with clinical manifestations that include flushing, persistent facial edema, dryness, burning and stinging skin, inflammatory papules and pustules, telangiectasia or dilation of blood vessels, and watery or irritated eyes.\(^3\) Up to 50% of patients with rosacea can also have ocular involvement.\(^4,5\) Rosacea has a negative impact on quality of life. Some studies have reported higher rates of depression in patients with rosacea.\(^2\) In a survey by the National Rosacea Society involving more than 400 patients, 75% of respondents reported that rosacea lowered their self-esteem and the majority of patients reported embarrassment and frustration.\(^4\)

There are multiple risk factors for the development of rosacea, including age, gender, and ultraviolet (UV) exposure. The onset of rosacea is generally between 30 and 50 years of age; it is less frequently reported in children and adolescents.\(^2,4\) The gender distribution is generally equal or female-predominant.\(^2\) UV exposure is a commonly-accepted risk factor, although the pathogenic relationship remains unknown. UV exposure may also induce rosacea by triggering innate immune responses. The cause of rosacea is unclear, but the pathogenesis of rosacea includes aberrations in innate immunity, dermal matrix degradation, and vasodilation.\(^2,3\) Interactions between microbial organisms may also play a role.\(^6\) Antimicrobial peptides, processing enzymes, and toll-like receptors may be involved in promoting inflammation in rosacea skin.\(^3\) The role of Demodex folliculorum, a house mite, has been reviewed and studies have suggested a temporal relationship between Demodex infestation and rosacea.\(^2\) Furthermore, Demodex harbors a gram-negative bacterium, Bacillus oleronius, which
produces proinflammatory proteins. Taphylococcus epidermis bacteria have also been isolated from pustules in some patients with papulopustular rosacea.

In 2002, rosacea was divided into four subtypes. However, many patients present with more than one subtype. Subtype 1 or erythematotelangiectatic rosacea is most common and is characterized by flushing and persistent facial erythema; other features include edema and roughness or scaling. The prevalence of subtype 1 is estimated to be approximately 4-fold greater than that for subtype 2. Subtype 2 or papulopustular rosacea is characterized by persistent central facial erythema with transient papules/pustules in a central facial distribution. Some patients have subtypes 1 and 2 rosacea; other patients develop subtype 2 rosacea following subtype 1 rosacea. Subtype 3 or phymatous rosacea is rather uncommon and is characterized by thickened skin with irregular nodules and localized enlargement. Of the subtypes, this subtype usually occurs in men. Subtype 4 or ocular rosacea is diagnosed based on one or more ocular-related manifestations, including: watery or bloodshot appearance, foreign body sensation, burning or stinging, dryness, itching, light sensitivity, blurring of vision, and corneal complications (including corneal infiltrate ulcers and keratitis).

The goal of therapy is to manage the clinical signs and the physical symptoms of rosacea. Non-pharmacologic modalities include: avoidance of triggers (e.g., extreme hot or cold temperature, wind, sun exposure); dietary changes (avoid spicy foods, alcohol); and use of daily sunscreen and gentle cleansers. Proper skin care is also necessary to control rosacea. Good skin care is imperative for the overall management of rosacea symptoms; a good skin regimen has been shown to improve therapeutic outcomes and to reduce skin irritation. At this time, there are no comparative studies to definitively recommend particular skin products; a regimen should be selected based on its ability to enhance skin hydration and reduce the likelihood of skin irritation associated with topical medication application.

References

10. MetroGel® 1% [prescribing information]. Fort. Worth, TX: Galderma; June 2012.


25. Colon LE, Johnson LA, Gottschalk RW. Cumulative irritation potential among metronidazole gel 1%, metronidazole gel 0.75%, and azelaic acid gel 15%. Cutis. 2007;79:317-321.

26. Metronidazole 0.75% gel [prescribing information]. Mason, OH: Prasco Laboratories; September 2014.