Topical Products for Rosacea

Policy Number: 5.01.509  Last Review: 10/2017
Origination: 10/2015  Next Review: 10/2018

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for brand name topical Rosacea products when the following criteria are met.

- Finacea® gel (azelaic acid 15% – Bayer Healthcare)
- Finacea® Plus Kit (azelaic acid gel 15% – Intendis, Inc)
- MetroCream® (metronidazole cream 0.75% – Galderma, generics)
- MetroGel® (metronidazole gel 1% – Galderma, generics)
- MetroLotion® (metronidazole lotion 0.75% – Galderma, generics)
- Noritate® (metronidazole cream 1% – Valeant)
- Rosadan® Kits (metronidazole 0.75% gel or 0.75% cream and Rehyla™ Wash – MediMetriks)
- Soolantra® (ivermectin cream 1% – Galderma)
- Finacea® foam (azelaic acid aerosol 15% – Bayer Healthcare)

When Policy Topic is covered
A step therapy program has been developed to encourage the use of a generic Step 1 product prior to the use of a Step 2 product. If the step therapy rule is not met for a Step 2 agent at the point of service, coverage will be determined by the step therapy criteria below. All approvals are provided for 1 year in duration.

**Step 1:** Metronidazole cream 0.75%, Metronidazole gel 0.75% and 1%, Metronidazole lotion 0.75% Rosadan cream, Rosadan gel

**Step 2:** Finacea gel, Finacea Plus Kit, Finacea foam, MetroCream, MetroGel, MetroLotion, Noritate Cream, Rosadan Cream Kit, Rosadan Gel Kit, Soolantra

Criteria
1. If a patient has used one Step 1 product, then authorization for a Step 2 product may be given.

2. No other exceptions are recommended.

When Policy Topic is not covered
Brand name Rosacea products are considered not medically necessary when the above criteria is not met

Considerations
This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.
**Description of Procedure or Service**

The metronidazole products are available generically as 0.75% cream, gel, and lotion and 1% gel; as brand Noritate® cream; and as a kit (Rosadan® cream or gel with a Rehyla™ wash [moisturizing wash]). These products are indicated for the treatment of inflammatory papules and pustules of rosacea; Noritate is also indicated for the treatment of erythema of rosacea. The metronidazole 0.75% products are to be applied twice daily (BID) [morning and evening] and the 1% products are to be applied once daily (QD). Like metronidazole, Finacea® gel, Finacea® foam, and Soolantra® are indicated for the treatment of inflammatory lesions of rosacea. The Finacea Plus Kits contain Finacea gel, CeraVe® moisturizing lotion, and CeraVe® hydrating cleanser. Finacea gel and Finacea foam are to be applied BID and Soolantra is to be applied QD.

The metronidazole products and Finacea (gel and foam) are in the Food and Drug Administration (FDA) pregnancy category B and Soolantra is in the pregnancy category C. The most common adverse events (AEs) associated with these agents are local skin-related AEs (e.g., skin burning/stinging/tingling, skin irritation, scaling/dry skin/xerosis, and pruritus).

Table 1 provides a comparison of topical metronidazole, Finacea (gel and foam), and Soolantra.

**Rationale**

Rosacea is a chronic, inflammatory facial skin disorder affecting approximately 16 million people in the US. Rosacea is more common in fair-skinned people of Northern and Eastern European descent, but it has been reported in people of other ethnicities. The hallmark of rosacea is central facial persistent erythema, typically affecting the cheeks, chin, forehead, and nose. 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.

The goal of therapy is to manage the clinical signs and 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.

The American Acne & Rosacea Society (AARS) published consensus guidelines on the management of rosacea in 2014 (Soolantra is not addressed in the guidelines). The consensus management recommendations are grouped based on two major common clinical presentations of rosacea: centrofacial erythema with papulopustular lesions and centrofacial erythema without papulopustular lesions. The guidelines note topical metronidazole and Finacea (formulation not noted) as the primary pharmacologic choices for the treatment of patients with mild, moderate, or severe centrofacial erythema with papulopustular lesions.

<p>| Table 1. Comparison of Topical Metronidazole Cream, Finacea, and Soolantra |
|---------------------------------|---------------------------------|---------------------------------|
| <strong>FDA-approved Indications</strong>    | <strong>Metronidazole Products</strong>      | <strong>Finacea® gel, Finacea® foam</strong> |
|                                 | Metronidazole cream 0.75%, gel 0.75% and 1%, lotion 0.75%: For the topical treatment of inflammatory papules and pustules of rosacea. Noritate: For the topical treatment of inflammatory lesions and erythema of | For the topical treatment of inflammatory papules and pustules of mild to moderate rosacea. |
|                                 | Soolantra® (ivermectin cream, 1%) | For the treatment of inflammatory lesions of rosacea. |</p>
<table>
<thead>
<tr>
<th>Metronidazole Products</th>
<th>Finacea® gel, Finacea® foam (azelaic acid, 15%)</th>
<th>Soolantra® (ivermectin cream, 1%)</th>
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</thead>
<tbody>
<tr>
<td>dosing</td>
<td>Metronidazole cream 0.75%, gel 0.75%, lotion 0.75%: Apply and rub in a thin layer BID (morning and evening) to the entire affected areas after washing with a mild cleanser. Metronidazole gel 1%, Noritate: Apply and rub in a thin layer QD to the entire affected areas after washing with a mild cleanser.</td>
<td>Gently massage/apply a thin layer of Finacea into the affected areas on the face BID (morning and evening) after washing with a mild soap/soapless cleanser.</td>
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<tr>
<td>mechanism of action</td>
<td>Unknown; may include an anti-inflammatory effect.</td>
<td>Unknown.</td>
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<td>clinical efficacy (reported from the PI)</td>
<td>In the MetroGel vs. vehicle-controlled trial:  - At Week 10, MetroGel was associated with a greater mean reduction of inflammatory lesions: 9.4 vs. 5.6 for vehicle. - More patients in the MetroGel group achieved IGA success: 38.4% of patients vs. 27.5% of patients in the vehicle group.</td>
<td>Gel:  - Finacea was significantly better than vehicle in reducing the number of inflammatory lesions: Study 1, 57.9% vs. 39.9%; Study 2, 50.0% vs. 38.2%. - Finacea was significantly better than vehicle in achieving IGA success: Study 1, 61% vs. 40%, respectively; Study 2, 61% vs. 48%. Foam:  - Finacea was superior compared with vehicle in reducing the number of inflammatory lesions: Study 1, -13.2 vs. -10.3 lesions; Study 2, -13.3 vs. -9.5 lesions. - Finacea was also superior compared with vehicle in achieving IGA success: Study 1, 32.1% vs. 23.4%; Study 2, 43.4% vs. 32.5%.</td>
</tr>
<tr>
<td>Contraindications</td>
<td>Hypersensitivity to metronidazole or other ingredients of the formulation.</td>
<td>Gel: Hypersensitivity to propylene glycol or any other component of the formulation. Foam: None are noted in the PI.</td>
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<tr>
<td>Warnings/ Precautions</td>
<td>• Use with care in patients with evidence of or history of blood dyscrasia. • Oral metronidazole can potentiate the anticoagulant effect of warfarin and coumarin anticoagulants, resulting in prolongation of PT. The effect of topical metronidazole on PT is unknown.</td>
<td>• There have been reports of hypopigmentation after use of azelaic acid (gel and foam).</td>
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<tr>
<td>FDA Pregnancy Category</td>
<td>B</td>
<td>B</td>
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</table>

FDA – Food and Drug Administration; BID – Twice daily; QD – Once daily; PI – Prescribing information; IGA – Investigator’s Global Assessment; PT – Prothrombin time.

REFERENCES
11. Soolantra® cream [prescribing information]. Fort Worth, TX: Galderma; December 2014.
New policy titled Topical Products for Rosacea

Annual review- no changes to policy statement

Annual review- no changes to policy statement

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