Clinical Guideline



Oscar Clinical Guideline: Ivermectin 1% Topical Cream (PG239, Ver. 1)

Ivermectin 1% Topical Cream

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Rosacea is a chronic inflammatory skin condition primarily affecting the central face. It is characterized by flushing, persistent erythema, telangiectasia, and inflammatory papules and pustules. The exact cause is unknown, but factors such as genetics, immune system dysfunction, and microbial imbalances may contribute. Treatment options include topical therapies (metronidazole, azelaic acid, ivermectin), oral antibiotics (doxycycline, minocycline), and in severe cases, oral isotretinoin.

Ivermectin 1% cream (Soolantra) is a semi-synthetic derivative with both anti-inflammatory and antiparasitic properties. It is FDA-approved for the treatment of inflammatory lesions of rosacea. Ivermectin cream is typically used after failure of or in conjunction with other topical therapies and may be an alternative to systemic treatments in some patients.

Definitions

"Inflammatory lesions of rosacea" refers to papules and pustules on the face associated with rosacea.

"Papulopustular rosacea" is a subtype of rosacea characterized by papules (red bumps) and pustules (pus-filled bumps) in addition to persistent central facial erythema.

"Persistent erythema" is lasting redness of the facial skin that is characteristic of rosacea.

"Rosacea" is a skin condition primarily affecting the face and can present as redness, swelling, inflammation that includes papules and pustules, dilated blood vessels that appear on the surface of the skin, and rhinophyma (characterized by an enlarged, red nose).

"Telangiectasia" refers to visible dilated blood vessels near the surface of the skin, commonly seen in rosacea.

Medical Necessity Criteria for Initial Authorization

The Plan considers <u>Ivermectin 1% Topical Cream</u> medically necessary when **ALL** of the following criteria are met:

- 1. The member is 18 years of age or older; AND
- 2. The member has a diagnosis of rosacea with inflammatory lesions (papules and pustules); AND
- 3. The member is unable to use, or has tried and failed at least **TWO** of the following:
 - a. Metronidazole 0.75% or 1%; and/or
 - b. Azelaic acid 15% 1; and/or
 - ¹NOTE: Prior authorization may be required.
 - c. Oral antibiotics (e.g., doxycycline, minocycline).

If the above prior authorization criteria are met, the requested product will be authorized for 12-months.

Medical Necessity Criteria for Reauthorization

Reauthorization for 12 months will be granted if the member has recent (within the last 3 months) clinical chart documentation indicating the member is responding positively to therapy as evidenced by reduction in inflammatory lesions.

Experimental or Investigational / Not Medically Necessary

Ivermectin 1% Topical Cream for any other indication or use is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven. Non-covered indications include, but are not limited to, the following:

- Treatment of acne vulgaris
- Treatment of flushing or persistent erythema associated with rosacea without inflammatory lesions
- Treatment of ocular rosacea
- Treatment of perioral dermatitis
- Treatment of rhinophyma
- Treatment of seborrheic dermatitis

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Clinical Guideline Revision / History Information

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