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 face. It is characterized by redness, swelling, telangiectasia (dilated blood vessels that appear on the surface of the skin), inflammatory papules and pustules, and rhinophyma (characterized by an enlarged, red nose). The exact cause is unknown, but factors such as genetics, immune system dysfunction, and microbial imbalances may contribute. Rosacea is managed by non-pharmacological (e.g., avoiding triggers of flushing, gentle skin care, sun-protection), laser and light therapy, and pharmacological therapy such as topical brimonidine, topical antimicrobials, topical azelaic acid, topical oxymetazoline, and oral antibiotics. The first-line treatment for mild-to-moderate disease, including inflammatory papules and pustules, include topical agents such as metronidazole, azelaic acid gel, topical ivermectin, sulfacetamide-sulfur, and erythromycin. Topical ivermectin can be used to improve symptoms of stinging, burning, and eyelid inflammation.

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.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Rosacea

The Plan considers **Ivermectin 1% Topical Cream** 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 **TWO (2)** of the following[s]:
    a. Metronidazole 0.75% or 1%; ***and/or***
    b. Azelaic acid 15%[~]; ***and/or***
    [~]*NOTE: Prior authorization may be required.*
    c. Oral antibiotics (e.g., doxycycline, minocycline); ***AND***
4. Ivermectin 1% topical cream is being prescribed at a dose and frequency that is within FDA approved labeling **OR** is supported by compendia or evidence-based published dosing guidelines for the requested indication; AND
    The requested medication is being used within the Plan's Quantity Limit of: 1 tube every 30 days.

If the above prior authorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Rosacea

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

1. The member meets the above applicable Initial Clinical Review; ***AND***
2. 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.

If the above reauthorization criteria are met, the requested product will be authorized for up to 12-months.[s]

Experimental / Investigational, unproven[s]

Ivermectin 1% Topical Cream for any other use is considered experimental, investigational, or unproven. Non-covered uses include, but are not limited to, the following:

- Treatment of acne vulgaris. There is not enough high quality evidence to support the safety and efficacy of ivermectin 1% topical cream for the management of acne vulgaris.
- Treatment of flushing or persistent erythema associated with rosacea without inflammatory lesions. Ivermectin 1% topical cream is only approved for those with inflammatory lesions (papules and pustules). There is no high quality evidence to support the safety and efficacy of ivermectin 1% topical cream for the management of flushing or persistent erythema associated with rosacea without inflammatory lesions.
- Treatment of perioral dermatitis. Only low quality evidence (case reports, case series) have supported the use of ivermectin 1% topical cream for perioral dermatitis. There is not enough evidence to support the safety and efficacy of ivermectin 1% topical cream for the management of perioral dermatitis.
- Treatment of rhinophyma. There is not enough high quality evidence to support the safety and efficacy of ivermectin 1% topical cream for the management of rhinophyma.
- Treatment of seborrheic dermatitis. There is no high quality evidence to support the safety and efficacy of ivermectin 1% topical cream for the management of seborrheic dermatitis.

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