

Policy and Procedure	
PHARMACY STEP THERAPY POLICY AND CRITERIA ORPTCINF025.1225	ANTI-INFECTIVE AGENT SOOLANTRA® (ivermectin cream)
Effective Date: 2/1/2026	Review/Revised Date: 06/15, 12/15, 10/17, 10/18, 05/19, 11/19, 10/20, 11/21, 10/22, 01/24, 10/24, 11/25 (JEF)
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Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:

Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Commercial

POLICY CRITERIA:

COVERED USES:

All Food and Drug Administration (FDA) approved indications not otherwise excluded from the benefit.

REQUIRED MEDICAL INFORMATION:

Documented intolerance, contraindication, or trial (defined as at least six weeks) to one of the following:

1. metronidazole topical gel, cream, or lotion
2. azelaic acid topical gel

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS: N/A

COVERAGE DURATION:

Authorization will be approved until no longer eligible with the plan, subject to formulary or benefit changes

QUANTITY LIMIT:

45 grams per 30 days

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy

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document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Soolantra® is the brand name for ivermectin cream which is FDA-approved to treat inflammatory lesions of rosacea.¹ Ivermectin is an antiparasitic medication and its mechanism of action for treating lesions of rosacea is unknown.¹

FDA APPROVED INDICATIONS:

Treatment of inflammatory lesions of rosacea

POSITION STATEMENT:

- Ivermectin cream was shown to reduce inflammatory lesions and lead to clear or almost clear skin in a greater percentage of subjects with rosacea, compared to vehicle cream².
- Ivermectin has been studied in a large number of subjects and was shown to be safe and effective for up to 52 weeks.²⁻³
- Ivermectin cream's effectiveness in reducing inflammatory lesions appears to be superior to topical metronidazole with a similar incidence of adverse events.³
- Topical metronidazole is indicated for the treatment of rosacea and is available in multiple vehicle preparations (cream, gel, and lotion), allowing for appropriate product selection based on patient-specific factors.⁴
- American Academy of Family Physicians (AAFP) guideline recommends first line therapy for mild to moderate inflammatory rosacea include topical metronidazole and azelaic acid.⁵
- Topical azelaic acid is indicated for treatment of rosacea and appears to be at least equally as effective as metronidazole.⁶

REFERENCE/RESOURCES:

1. Soolantra package insert. Fort Worth, TX: Galderma laboratories; 2024 October.
2. Gold LS, Kircik L, Fowler J, et al. Long-term safety of ivermectin 1% cream vs azelaic acid 15% gel in treating inflammatory lesions of rosacea: results of

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- two 40-week controlled, investigator-blinded trials. *J Drugs Dermatol.* 2014;13(11):1380-6.
3. Taieb A, Ortonne JP, Ruzicka T, et al, Superiority of ivermectin 1% cream over metronidazole 0.75% cream in treating inflammatory lesions of rosacea: a randomized, investigator-blind trial. *Br J Dermatol.* 2015;172:1103-10.
 4. MetroLotion package insert. Fort Worth, TX: Galderma laboratories; 2018 June.
 5. Oge' LK, Muncie HL, Phillips-Savoy AR. Rosacea: Diagnosis and Treatment. *Am Fam Physician.* 2015;92(3):187-196.
 6. van Zuuren EJ, Fedorowicz Z, Tan J, et al. Interventions for rosacea based on the phenotype approach: an updated systematic review including GRADE assessments. *Br J Dermatol.* 2019;181(1):65-79.