RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	ivermectin
Policy Number:	RxA.482
Drug(s) Applied:	Soolantra®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Ivermectin (Soolantra®) is a semi-synthetic derivative isolated from the fermentation of Streptomyces avermitilis that belongs to the avermectin family of macrocyclic lactones. It is indicated for the treatment of inflammatory lesions of rosacea.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
ivermectin (Soolantra®)	Rosacea	Apply pea size amount to the affected areas of the face once daily.	1 g/day

Dosage Forms

- Cream (30 g, 45 g, 60 g): 1%

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Rosacea (must meet all)**:**

1. Diagnosis of rosacea;
2. Age ≥ 18 years;
3. Failure of ≥ 6 consecutive weeks of one of the following (see Appendix B) at maximally tolerated doses unless contraindicated or clinically significant adverse effects are experienced: oral doxycycline, oral minocycline, topical metronidazole, or topical azelaic acid;
4. Dose does not exceed 1 tube per month.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. Rosacea (must meet all):
1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 tube per month.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

APPENDIX B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
metronidazole (Metrocream® 0.75%, Metrogel® 1%, Metrolotion®0.75%)	Apply thin film topically to affected area once daily for 1% and BID for 0.75%	Not applicable
azelaic acid (Finacea® 15% gel)	Apply in a thin film topically to the affected area BID Reassess if no improvement in 12 weeks	Not applicable
minocycline (Solodyn®)*	IR: 200 mg PO followed by 100 mg PO Q12H ER: 1 mg/kg PO once daily	350 mg on day 1, then 200 mg/day
doxycycline (Oracea®)	40 mg PO once daily in the morning (1 hour before or 2 hours after a meal)	300 mg/day PO; 40 mg PO/day for Oracea

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings
- Contraindication(s):
  - Ivermectin is contraindicated in patients with hypersensitivity to any component of the product.
- Boxed Warning(s):
  - None

APPENDIX D: General Information
- Patients with a history of severe asthma should receive ivermectin with caution. Occasionally,

systemic ivermectin has been reported to worsen bronchial asthma.

References

1. Soolantra® Prescribing Information. Fort Worth, TX: Galderma Laboratories LP; July 2018. Available at: http://www.galdermausa.com/pi/soolantrapi.pdf. Accessed September 04, 2020.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2019. Available at: http://www.clinicalpharmacology-ip.com. Accessed September 04, 2020.
3. Stein L, Kircik L, Fowler J, et al. Efficacy and safety of ivermectin 1% cream in treatment of papulopustular rosacea: results of two randomized, double-blind, vehicle-controlled pivotal studies. J Drugs Dermatol. 2014:13(3):316-323.
4. Oge' LK, Muncie HL, and Phillips-Savoy AR. Rosacea: diagnosis and treatment. American Family Physician. Am Fam Physician 2015;92(3):187-196.
5. Schaller M, Almeida LMC, Bewly A, et al. Rosacea treatment update: recommendations from the global ROSacea Consensus (ROSCO) panel. Br J Dermatol 2017; 176:465-471. DOI 10.1111/bjd.15173

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed 1. Policy title was updated. 2. Line of business policy applies to was updated to All lines of business. 3. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 4. Approval duration updated as 12 months for initial and continued therapy approval. 5. Appendix C updated for contraindication and appendix D added to the policy. 6. References were reviewed and updated.	09/04/2020	12/07/2020