Clinical Policy: Ivermectin (Soolantra)
Reference Number: CP.CPA.155
Effective Date: 11.16.16
Last Review Date: 11.18
Line of Business: Commercial

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Ivermectin (Soolantra®) is a semi-synthetic derivative isolated from the fermentation of Streptomyces avermitilis that belongs to the avermectin family of macrocyclic lactones.

FDA Approved Indication(s)
Soolantra is indicated for the treatment of inflammatory lesions of rosacea

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

It is the policy of health plans affiliated with Centene Corporation® that Soolantra is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Rosacea (must meet all):
      1. Diagnosis of rosacea;
      2. Age ≥ 18 years;
      3. Failure of ≥ 6 consecutive weeks of maximally tolerated doses of one of the following (see Appendix B) unless contraindicated or clinically significant adverse effects are experienced: oral doxycycline, oral minocycline, topical metronidazole, or Finacea®;
      4. Dose does not exceed 1 tube per month.

   Approval duration: Length of Benefit

   B. Other diagnoses/indications
      1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

II. Continued Therapy
   A. Rosacea (must meet all):
      1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
      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: Length of Benefit
B. Other diagnoses/indications (must meet 1 or 2):
   1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 12 months (whichever is less); or
   2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial.

III. Diagnoses/Indications for which coverage is NOT authorized:
   A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial or evidence of coverage documents.

IV. Appendices/General Information
   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.

<table>
<thead>
<tr>
<th>Drug Name</th>
<th>Dosing Regimen</th>
<th>Dose Limit/Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>metronidazole</td>
<td>Apply thin film topically to affected area QD for 1% and BID for 0.75%</td>
<td>No maximum dosage information is available.</td>
</tr>
<tr>
<td>(Metrocream®, 0.75%,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metrogel®, 1%,</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Metrolotion®, 0.75%)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Finacea® (15% gel)</td>
<td>Apply in a thin film topically to the affected area BID Reassess if no</td>
<td>No maximum dosage information is available.</td>
</tr>
<tr>
<td>(azelaic acid)</td>
<td>improvement in 12 weeks</td>
<td></td>
</tr>
<tr>
<td>minocycline</td>
<td>IR: 200 mg PO followed by 100 mg PO Q12H ER: 1 mg/kg PO QD</td>
<td>350 mg on day 1, then 200mg/day</td>
</tr>
<tr>
<td>(Minocin®, Solodyn®)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>doxycycline</td>
<td>Lesions (papules and pustules): 40 mg PO once daily in the morning (1 hour</td>
<td>300 mg/day PO; 40 mg PO/day for Oracea</td>
</tr>
<tr>
<td>(Oracea)®</td>
<td>before or 2 hours after a meal)</td>
<td></td>
</tr>
</tbody>
</table>

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
None reported
V. Dosage and Administration

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dosing Regimen</th>
<th>Maximum Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rosacea</td>
<td>Apply pea size amount to the affected areas of the face QD</td>
<td>1 g/day</td>
</tr>
</tbody>
</table>

VI. Product Availability
Cream: 1% (30 g, 45 g, 60 g)

VII. References

Reviews, Revisions, and Approvals

<table>
<thead>
<tr>
<th>Description</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Converted to new template. Minor changes to verbiage and grammar. References updated.</td>
<td>01.17.17</td>
<td>11.17</td>
</tr>
<tr>
<td>4Q 2018 annual review: added age limit; added 6-week duration of trial for redirection; added maximum dose per PI and dose optimization; references reviewed and updated.</td>
<td>09.04.18</td>
<td>11.18</td>
</tr>
<tr>
<td>No significant changes, generalized dosing limits to 1 tube as quantity limit varies by plan.</td>
<td>12.19.18</td>
<td></td>
</tr>
</tbody>
</table>

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.
The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

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