Clinical Policy: Ivermectin (Sklice)
Reference Number: HIM.PA.124
Effective Date: 12.01.17
Last Review Date: 08.20
Line of Business: HIM

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

Description
Ivermectin lotion (Sklice®) is a pediculicide.

FDA Approved Indication(s)
Sklice is indicated for the topical treatment of head lice infestations in patients 6 months of age and older.

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 Sklice is medically necessary when the following criteria are met:

I. Initial Approval Criteria
   A. Head Lice (must meet all):
      1. Diagnosis of head lice;
      2. Age ≥ 6 months;
      3. Failure of permethrin 1% cream, used in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced;
      4. Request does not exceed 1 tube for a single use.
   Approval duration: 14 days

   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): HIM.PHAR.21 for health insurance marketplace.

II. Continued Therapy
   A. Head Lice
      1. Re-authorization is not permitted. Members must meet the initial approval criteria.
   Approval duration: Not applicable

   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 14 days (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): HIM.PHAR.21 for health insurance marketplace.

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 – HIM.PHAR.21 for health insurance marketplace 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>permethrin 1%</td>
<td>Adults, adolescents, children, and infants ≥ 2 months: Shampoo hair with regular shampoo, rinse and towel dry. Then, apply permethrin 1% lotion sufficient to saturate the hair and scalp (usually 25 to 30 mL), especially behind the ears and on the nape of the neck. Leave on hair for 10 minutes but no longer. Then, rinse thoroughly with water. If live lice are seen 7 days or more after the first application, a second treatment should be given.</td>
<td>One application to affected area</td>
</tr>
<tr>
<td>cream rinse/lotion</td>
<td></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>Head lice</td>
<td>Apply to dry hair in an amount sufficient (up to 1 tube) to thoroughly coat the hair and scalp. Leave on the hair and scalp for 10 minutes, and then rinse off with water. The tube is intended for single use; discard any unused portion.</td>
<td>1 tube/topical application</td>
</tr>
</tbody>
</table>

VI. Product Availability
Lotion 0.5%: 177 g
VII. References

<table>
<thead>
<tr>
<th>Reviews, Revisions, and Approvals</th>
<th>Date</th>
<th>P&amp;T Approval Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Policy created</td>
<td>09.01.17</td>
<td>11.17</td>
</tr>
<tr>
<td>3Q 2018 annual review: modified timeframe of trial of permethrin from within the last 6 months to last 60 days; shortened approval duration from 1 month to 14 days since medication is intended for single use; continued therapy: removed requirement that 6 months should have elapsed since previous claim for Sklice; references reviewed and updated.</td>
<td>04.10.18</td>
<td>08.18</td>
</tr>
<tr>
<td>3Q 2019 annual review: no significant changes; references reviewed and updated.</td>
<td>05.21.19</td>
<td>08.19</td>
</tr>
<tr>
<td>3Q 2020 annual review: no significant changes; references reviewed and updated.</td>
<td>04.30.20</td>
<td>08.20</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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