Clinical Policy: Ivermectin (Stromectol, Sklice)

Reference Number: CP.PMN.269
Effective Date: 12.01.21
Last Review Date: 08.23
Line of Business: Commercial, HIM, Medicaid

Revision Log

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

Description

Ivermectin tablet (Stromectol®) is an anthelmintic agent.

Ivermectin lotion (Sklice®) is a pediculicide.

FDA Approved Indication(s)

Stromectol is indicated for the treatment of:

- Intestinal (i.e., nondisseminated) strongyloidiasis due to the nematode parasite *Strongyloides stercoralis*.
  - This indication is based on clinical studies of both comparative and open-label designs, in which 64-100% of infected patients were cured following a single 200 mcg/kg dose of ivermectin.
- Onchocerciasis due to the nematode parasite *Onchocerca volvulus*.
  - This indication is based on randomized, double-blind, placebo-controlled and comparative studies conducted in 1427 patients in onchocerciasis-endemic areas of West Africa. The comparative studies used diethylcarbamazine citrate (DEC-C).
  - Stromectol has no activity against adult *Onchocerca volvulus* parasites. The adult parasites reside in subcutaneous nodules which are infrequently palpable. Surgical excision of these nodules (nodulectomy) may be considered in the management of patients with onchocerciasis, since this procedure will eliminate the microfilariae-producing adult parasites.

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 ivermectin is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Head Lice (must meet all)**:**

1. Request is for ivermectin lotion;
2. Diagnosis of head lice;
3. Age ≥ 6 months;

4. Failure of permethrin 1% cream, used in the last 60 days, unless contraindicated or clinically significant adverse effects are experienced;
5. Request does not exceed 1 tube for a single use.

Approval duration: 14 days

B. All Other Indications (must meet all)**:**

1. Request is for generic ivermectin tablets;
2. Request is not for the prevention or treatment of coronavirus disease 2019 (COVID-19);
3. Dose does not exceed health plan quantity limit, if applicable.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Head Lice

1. Re-authorization is not permitted. Members must meet the initial approval criteria.

Approval duration: Not applicable

B. All Other Indications (must meet all)**:**

1. Request is for generic ivermectin tablets;
2. Request is not for the prevention or treatment of coronavirus disease 2019 (COVID-19);
3. If request is for a dose increase, new dose does not exceed health plan quantity limit, if applicable.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid

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, HIM.PA.154 for health insurance marketplace, and CP.PMN.53 for Medicaid, or evidence of coverage documents;

B. Ivermectin tablets for the prevention or treatment of coronavirus disease 2019 (COVID-19).

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.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
permethrin 1% cream rinse/lotion	**Head lice** 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.	One application to affected area

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

Appendix D: General Information
- The National Institutes of Health Coronavirus Disease 2019 (COVID-19) Treatment Guidelines and World Health Organization (WHO) Therapeutics and COVID-19 living guidelines recommend against the use of ivermectin tablets for the prevention or treatment COVID-19 at this time due to insufficient evidence regarding the benefits and harms of the treatment based on current evidence.

V. Dosage and Administration

<table>
<tr><th>Drug Name</th><th>Indication</th><th>Dosing Regimen</th><th>Maximum Dose</th></tr>
<tr><td rowspan="2">Ivermectin (Stromectol) tablets</td><td>Onchocerciasis</td><td>Doses should be prescribed to provide approximately 150 mcg of ivermectin per kg of body weight:
<table><tr><th>Body Weight (kg)</th><th>Single Oral Dose Number of 3-mg Tablet(s)</th></tr><tr><td>15 to 25</td><td>1 tablet</td></tr><tr><td>26 to 44</td><td>2 tablets</td></tr><tr><td>45 to 64</td><td>3 tablets</td></tr><tr><td>65 to 84</td><td>4 tablets</td></tr><tr><td>≥ 85</td><td>150 mcg/kg</td></tr></table></td><td>150 mcg/kg/dose</td></tr>
<tr><td>Strongyloidiasis</td><td>Doses should be prescribed to provide approximately 200 mcg of ivermectin per kg of body weight:
<table><tr><th>Body Weight (kg)</th><th>Single Oral Dose Number of 3-mg Tablet(s)</th></tr><tr><td>15 to 24</td><td>1 tablet</td></tr><tr><td>25 to 35</td><td>2 tablets</td></tr><tr><td>36 to 50</td><td>3 tablets</td></tr><tr><td>51 to 65</td><td>4 tablets</td></tr><tr><td>66 to 79</td><td>5 tablets</td></tr><tr><td>≥ 80</td><td>200 mcg/kg</td></tr></table></td><td>200 mcg/kg/dose</td></tr>
<tr><td>Ivermectin (Sklice) lotion 0.5%</td><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.</td><td>1 tube/ topical application</td></tr>
</table>

Drug Name	Indication	Dosing Regimen	Maximum Dose
		The tube is intended for single use; discard any unused portion.	

VI. Product Availability

Drug Name	Availability
Ivermectin (Stromectol)	Tablet: 3 mg
Ivermectin (Sklice)	Lotion 0.5%: 117 g (tube)

VII. References

1. Stromectol Prescribing Information. Whitehouse Station, NJ: Merck Sharp & Dohme BV.; March 2022. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/050742s030lbl.pdf. Accessed April 20, 2023.
2. Sklice Prescribing Information. Atlanta, CA: Arbor Pharmaceuticals, LLC.; June 2017. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2017/202736s003lbl.pdf. Accessed April 20, 2023.
3. Centers for Disease Control and Prevention. Parasites-Lice-Head Lice. Available at: https://www.cdc.gov/parasites/lice/head/treatment.html. Updated October 15, 2019. Accessed April 20, 2023.
4. Devore CD, Schutze GE. Council on School Health and Committee on Infectious Diseases, American Academy of Pediatrics. Head lice. Pediatrics. 2015; 135(5):e1355-e1365.
5. COVID-19 Treatment Guidelines Panel. Coronavirus Disease 2019 (COVID-19) Treatment Guidelines. National Institutes of Health. Available at: https://files.covid19treatmentguidelines.nih.gov/guidelines/covid19treatmentguidelines.pdf. Accessed April 20, 2023.
6. World Health Organization. Therapeutics and COVID-19: living guideline. Last updated on January 13, 2023. Available at: https://www.who.int/publications/i/item/WHO-2019-nCoV-therapeutics-2022.4. Accessed April 20, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created; adopted from HIM.PA.124 ivermectin (HIM.PA.124 to be retired); added criteria for ivermectin tablets.	09.23.21	11.21
3Q 2022 annual review: no significant changes; references reviewed and updated.	05.12.22	08.22
Template changes applied to other diagnoses/indications.	10.06.22	
3Q 2023 annual review: no significant changes; references reviewed and updated.	04.20.23	08.23

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.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.