

## Clinical Policy: Ivermectin (Stromectol, Sklice)

Reference Number: ERX.NPA.79

Effective Date: 09.01.18

Last Review Date: 11.21

Line of Business: Commercial, Medicaid

[Revision Log](#)

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

### Description

Ivermectin tablet (Stromectol<sup>®</sup>) is an anthelmintic agent.

Ivermectin (Sklice<sup>®</sup>) 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).
  - Limitation(s) of use: 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.*

*Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.*

It is the policy of health plans affiliated with Envolve Pharmacy Solutions<sup>™</sup> 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  $\geq$  6 months;
4. Failure of malathion or spinosad, used in the last 60 days, unless both are 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**

**B. Other diagnoses/indications**

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**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 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. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.

**Approval duration: Duration of request or 14 days (whichever is less); or**

2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

**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 policy – ERX.PA.01 or evidence of coverage documents.**

**IV. Appendices/General Information**

*Appendix A: Abbreviation/Acronym Key*

COVID-19: coronavirus disease 2019

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 and may require prior authorization.*

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
malathion (Ovide®)	<b>Head Lice</b> Adults, adolescents, and children ≥ 6 years: Apply to dry hair and scalp. Apply as a single topical application in a sufficient amount (roughly 30 mL) to saturate hair and scalp. Leave on hair for 8-12 hours but no longer. Then, rinse thoroughly and shampoo with a non-medicated shampoo. After rinsing, use a nit comb to remove the dead lice and the nits (eggs) from the hair. Retreatment is not frequently required. A second treatment may be given if live lice are seen 7-9 days or more after the first application.	1 application (roughly 30 mL) topically as directed.
spinosad (Natroba®)	<b>Head Lice</b> Adults, adolescents, children, and infants ≥ 6 months: Apply a sufficient amount of spinosad suspension to cover dry scalp and hair; up to one bottle (120 mL) may be required depending on the length of hair. Leave on for 10 minutes and then rinse	120 mL/application

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
	thoroughly with warm water. If live lice are still seen 7 days after the first treatment, apply a second treatment.	

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 COVID-19 Treatment Guidelines World Health Organization (WHO) Therapeutics and COVID-19 living guideline 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

Drug Name	Indication	Dosing Regimen	Maximum Dose													
Ivermectin (Stromectol) tablets	Onchocerciasis	Doses should be prescribed to provide approximately 150 mcg of ivermectin per kg of body weight:  <table border="1"> <thead> <tr> <th>Body Weight (kg)</th> <th>Single Oral Dose Number of 3-mg Tablet(s)</th> </tr> </thead> <tbody> <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> </tbody> </table>	Body Weight (kg)	Single Oral Dose Number of 3-mg Tablet(s)	15 to 25	1 tablet	26 to 44	2 tablets	45 to 64	3 tablets	65 to 84	4 tablets	≥ 85	150 mcg/kg	150 mcg/kg/dose	
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Ivermectin (Sklice) lotion 0.5%	Head lice	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.	1 tube/ topical application													
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#### VI. Product Availability

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

#### VII. References

1. Ivermectin Prescribing Information. Hawthorne, NY: Taro Pharmaceuticals U.S.A., Inc.; May 2020. Available at: <https://dailymed.nlm.nih.gov/dailymed/>. Accessed April 30, 2021.
2. 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 30, 2020.
3. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: <http://www.clinicalpharmacology-ip.com/>.
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. FDA Approves Lotion for Nonprescription Use to Treat Head Lice; October 27, 2020; <https://www.fda.gov/news-events/press-announcements/fda-approves-lotion-nonprescription-use-treat-head-lice#:~:text=Sklice%20will%20be%20marketed%20in,available%20as%20a%20prescription%20drug.>
6. 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 September 23, 2021.

7. World Health Organization. Therapeutics and COVID-19: living guideline. WHO/2019-nCoV/therapeutics/2021.2. Available at: <file:///C:/Users/cn110096/Downloads/WHO-2019-nCoV-therapeutics-2021.2-eng.pdf>. Accessed September 23, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created: adapted from ERX.ST.24; no significant changes; added diagnosis; references reviewed and updated.	04.10.18	08.18
3Q 2019 annual review: no significant changes; references reviewed and updated.	05.21.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.30.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	04.30.21	08.21
Added criteria for ivermectin tablets.	09.23.21	11.21

**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.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. 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.

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