

Clinical Policy: Ivermectin (Stromectol, Sklice)

Reference Number: CP.PMN.269

Effective Date: 12.01.21

Last Review Date: 11.21

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).
 - 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.

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 \geq 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

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, 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. 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, 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 \geq 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 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:	150 mcg/kg/dose

Drug Name	Indication	Dosing Regimen		Maximum Dose
		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	
	Strongyloidiasis	Doses should be prescribed to provide approximately 200 mcg of ivermectin per kg of body weight:		200 mcg/kg/dose
		Body Weight (kg)	Single Oral Dose Number of 3-mg Tablet(s)	
		15 to 24	1 tablet	
		25 to 35	2 tablets	
		36 to 50	3 tablets	
		51 to 65	4 tablets	
		66 to 79	5 tablets	
≥ 80	200 mcg/kg			
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

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; adopted from HIM.PA.124 ivermectin (HIM.PA.124 to be retired); 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. 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.

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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.

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