

## Clinical Policy: Ivermectin tablet (Stromectol)

Reference Number: PA.CP.PMN.269

Effective Date: 08/2022

Last Review Date: 08/2024

### Description

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

### 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.

### 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 PA Health & Wellness<sup>®</sup> that ivermectin is **medically necessary** when the following criteria are met:

#### I. Initial Approval Criteria

##### A. All Other Indications, other than COVID-19 (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 the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

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## II. Continued Therapy

### A. 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**

### B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;

**Approval duration: Duration of request or 12 months (whichever is less); or**

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

## 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 – PA.CP.PMN.53.

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*

*Not applicable*

*Appendix C: Contraindications/Boxed Warnings*

- Contraindication(s): Hypersensitivity to any component of the product (*Stromectol only*)
- Boxed warning(s): 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.

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## 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	
	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:  <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 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> </tbody> </table>	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	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															

## VI. Product Availability

Drug Name	Availability
Ivermectin (Stromectol)	Tablet: 3 mg

## 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/2022/050742s0301bl.pdf](https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/050742s0301bl.pdf). Accessed May 13, 2024.
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 May 21, 2024.
3. 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.
4. 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-2022.3>. Accessed May 21, 2024.

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<b>Reviews, Revisions, and Approvals</b>	<b>Date</b>
Policy created	07/2022
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023
3Q 2024 annual review: no significant changes; updated Appendix C; references reviewed and updated.	07/2024