Clinical Policy: Ivermectin tablet (Stromectol)

Reference Number: PA.CP.PMN.269
Effective Date: 08/2022
Last Review Date: 08/2023

Revision Log

Description
Ivermectin tablet (Stromectol®) 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® 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.

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.LTSS.PHAR.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
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

<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>
</table>

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/2022/050742s030lbl.pdf. Accessed April 20, 2023.
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 20, 2023.
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. 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.
5. 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 April 20, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	07/2022	
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023	