# **PRIOR AUTHORIZATION POLICY**

**POLICY:** Infectious Disease – Ivermectin Tablets Prior Authorization Policy

• Stromectol<sup>®</sup> (ivermectin tablets – Merck, generic)

**REVIEW DATE:** 02/28/2024

#### **OVERVIEW**

Ivermectin tablets (Stromectol, generic), an anthelmintic, are indicated for the treatment of intestinal (i.e., non-disseminated) **strongyloidasis** due to the nematode parasite *Strongyloides stercoralis* and for the treatment of **onchocerciasis** due to the nematode parasite *Onchocerca volvulus*. Ivermectin tablets do not have any activity against adult *O. volvulus* parasites and surgical excision of *O. volvulus* nodules is the recommended treatment.

The prescribing information notes that ivermectin tablets are given as a single oral dose for these two indications.<sup>1</sup> However, other sources note that ivermectin tablets should be given for 2 days for the treatment of strongyloidiasis.<sup>1-3</sup>

## **Off-Label Uses**

Ivermectin has been used for many parasitic infections (off-label).<sup>2,3-6</sup> The Centers for Disease Control and Prevention (CDC) notes ivermectin tablets as a treatment option for the following: ascariasis, gnathostomiasis, hookworm-related cutaneous larva migrans, pediculosis (*pediculus humanus capitis*, *pediculus humanus corporis*, and pediculosis pubis [due to *Phthirus pubis*]), scabies, trichuriasis, and *Wucheria bancrofti* infection (a main cause of lymphatic filariasis).<sup>7-15</sup> There are data to support the use of ivermectin tablets for the treatment of enterobiasis, *Demodex folliculorum*, *Mansonella ozzardi* and *M. streptocerca* infections.<sup>6,16</sup>

#### POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ivermectin tablets. All approvals are provided for 1 month (30 days), which is an adequate duration of time for the patient to receive the required number of doses.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Ivermectin tablets is recommended in those who meet one of the following criteria:

# **FDA-Approved Indications**

- **1. Onchocerciasis Infection.** Approve for one month.
- **2. Strongyloidiasis.** Approve for one month.

# **Other Uses with Supportive Evidence**

- **3. Ascariasis.** Approve for one month.
- **4.** *Demodex folliculorum* **infection.** Approve for one month.
- **5. Enterobiasis** (**pinworm infection**). Approve for one month.
- **6. Gnathostomiasis.** Approve for one month.
- 7. Hookworm-related cutaneous larva migrans. Approve for one month.
- **8.** *Mansonella ozzardi* infection. Approve for one month.
- **9.** *Mansonella streptocerca* infection. Approve for one month.
- 10. Pediculosis. Approve for one month if the patient meets one of the following (A, B, or C):
  - A) Patient has infection caused by *pediculus humanus capitis* (head lice); OR
  - **B**) Patient has infection caused by *pediculus humanus corporis* (body lice); OR
  - C) Patient has pediculosis pubis caused by *Phthirus pubis* (pubic lice).
- 11. Scabies. Approve for one month if the patient meets one of the following (A, B, C, D, or E):
  - A) Patient has classic scabies; OR
  - B) Patient has treatment-resistant scabies; OR
  - C) Patient is unable to tolerate topical treatment; OR
  - **D**) Patient has crusted scabies (i.e., Norwegian scabies); OR
  - E) Patient is using ivermectin tablets for prevention and/or control of scabies.
- **12. Trichuriasis.** Approve for one month.
- **13.** *Wucheria bancrofti* **infection.** Approve for one month.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Ivermectin tablets is not recommended in the following situations:

- 1. Coronavirus disease 2019 (COVID-19). The CDC's COVID-19 Treatment Guideline Panel reviewed studies that assessed the efficacy of oral ivermectin in the treatment of COVID-19.<sup>17</sup> The Panel reviewed data from several clinical trials and cited the following findings: oral ivermectin did not reduce the need for emergency setting visits or hospitalizations when compared with placebo; there was no evidence of virologic or clinical benefit of using oral ivermectin; there was no evidence that oral ivermectin reduced progression to severe disease, improve time to resolution of symptoms; and compared with standard of care, oral ivermectin did not result in differences in all-cause mortality, hospital length of stay, or the need for mechanical ventilation. The Panel recommends against the use of ivermectin for the treatment of COVID-19, except in clinical trials.
- **2.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

#### REFERENCES

- 1. Stromectol® tablets [prescribing information]. Whitehouse Station, NJ: Merck; May 2022.
- 2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2024. Available at: <a href="https://www.clinicalkey.com/pharmacology/">https://www.clinicalkey.com/pharmacology/</a>. Accessed on February 23, 2024. Search term: ivermectin.
- 3. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2024. Available at: <a href="http://fco.factsandcomparisons.com/lco/action/home">http://fco.factsandcomparisons.com/lco/action/home</a>. Accessed on February 23, 2024. Search term: ivermectin.
- Centers for Disease Control and Prevention. Parasites Onchocerciasis (also known as river blindness). Available at: <a href="https://www.cdc.gov/parasites/onchocerciasis/">https://www.cdc.gov/parasites/onchocerciasis/</a>. Accessed on February 23, 2024.
- Centers for Disease Control and Prevention. Chapter 4. Travel-related infectious diseases. Available at https://wwwnc.cdc.gov/travel/yellowbook/2024/infections-diseases/strongyloidiasis. Accessed on February 23, 2024.
- Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <a href="https://www.micromedexsolutions.com/">https://www.micromedexsolutions.com/</a>. Accessed on September 7, 2022. Search term: ivermectin.
- Centers for Disease Control and Prevention. Parasites Ascariasis. Available at: https://www.cdc.gov/parasites/ascariasis/index.html. Accessed on February 23, 2024.
- Centers for Disease Control and Prevention. Parasites Gnathostomiasis. Available at: <a href="https://www.cdc.gov/parasites/gnathostoma/health-professionals">https://www.cdc.gov/parasites/gnathostoma/health-professionals</a>. Accessed on February 23, 2024.
- Centers for Disease Control and Prevention. Parasites Zoonotic Hookworm. Available at: <a href="https://www.cdc.gov/parasites/zoonotichookworm/health-professionals/index.html#tx">https://www.cdc.gov/parasites/zoonotichookworm/health-professionals/index.html#tx</a>. Accessed on February 23, 2024.
- 10. Centers for Disease Control and Prevention. Parasites Head Lice. Available at: <a href="https://www.cdc.gov/parasites/lice/head/index.html">https://www.cdc.gov/parasites/lice/head/index.html</a>. Accessed on February 23, 2024.
- 11. Centers for Disease Control and Prevention. Parasites Body Lice. Available at: https://www.cdc.gov/parasites/lice/body/treatment.html. Accessed on February 23, 2024.
- 12. Centers for Disease Control and Prevention. Parasites Pubic "Crab" Lice. Available at: <a href="https://www.cdc.gov/parasites/lice/pubic/index.html">https://www.cdc.gov/parasites/lice/pubic/index.html</a>. Accessed on February 23, 2024.
- 13. Centers for Disease Control and Prevention. Parasites Scabies. Available at: <a href="https://www.cdc.gov/parasites/scabies/index.html">https://www.cdc.gov/parasites/scabies/index.html</a>. Accessed on February 23, 2024.
- 14. Centers for Disease Control and Prevention. Parasites Trichuriasis (also known as whipworm infection). Available at: <a href="https://www.cdc.gov/parasites/whipworm/health-professionals/index.html">https://www.cdc.gov/parasites/whipworm/health-professionals/index.html</a>. Accessed on February 23, 2024.
- 15. Centers for Disease Control and Prevention. Parasites Lymphatic filariasis. Available at: <a href="https://www.cdc.gov/parasites/lymphaticfilariasis/">https://www.cdc.gov/parasites/lymphaticfilariasis/</a>. Accessed on February 23, 2024.
- 16. Ta-Ting TH, Crainey JL, Post RJ, et al. Mansonellosis: current perspectives. Res Rep Trop Med. 2018;9:9-24.
- Centers for Disease Control and Prevention COVID-19 Treatment Guidelines Ivermectin. Last updated December 20, 2023. Available at: <a href="https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/">https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/</a>. Accessed on February 23, 2024.