

PRIOR AUTHORIZATION POLICY

POLICY: Infectious Disease – Ivermectin Tablets Prior Authorization Policy

- Stromectol® (ivermectin tablets – Merck, generic)

REVIEW DATE: 09/14/2022

OVERVIEW

Ivermectin tablets (Stromectol, generic), an anthelmintic, are indicated for the treatment of intestinal (i.e., non-disseminated) **strongyloidiasis** due to the nematode parasite *Strongyloides stercoralis* and for the treatment of **onchocerciasis** due to the nematode parasite *Onchocerca volvulus*.¹ 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.¹ However, other sources note that ivermectin tablets should be given for 2 days for the treatment of strongyloidiasis.¹⁻³

Off-Label Uses

Ivermectin has been used for many parasitic infections (off-label).^{2,3,6} 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).⁷⁻¹⁵ There are data to support the use of ivermectin tablets for the treatment of enterobiasis, *Demodex folliculorum*, and *Mansonella ozzardi* and *M. streptocerca* infections.^{6,16}

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of ivermectin tablets. All approvals are provided for 30 days, which is an adequate duration 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 dose.
2. **Strongyloidiasis.** Approve for two doses.

Other Uses with Supportive Evidence

3. **Ascariasis.** Approve for one dose.
4. ***Demodex folliculorum* infection.** Approve for two doses.
5. **Enterobiasis (pinworm infection).** Approve for two doses.
6. **Gnathostomiasis.** Approve for one dose.
7. **Hookworm-related cutaneous larva migrans.** Approve for one dose.
8. ***Mansonella ozzardi* infection.** Approve for one dose.
9. ***Mansonella streptocerca* infection.** Approve for one dose.
10. **Pediculosis.** Approve for three doses 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 the duration noted below if the patient meets one of the following (A, B, C, D, or E):
 - A) Patient has classic scabies: Approve for two doses; OR
 - B) Patient has treatment-resistant scabies: Approve for two doses; OR
 - C) Patient is unable to tolerate topical treatment: Approve for two doses; OR
 - D) Patient has crusted scabies (i.e., Norwegian scabies): Approve for five doses; OR
 - E) Patient is using ivermectin tablets for prevention and/or control of scabies: Approve one dose.
12. **Trichuriasis.** Approve for three doses.
13. ***Wucheria bancrofti* infection.** Approve for one dose.

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-19.¹⁷ 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.; 2022. Available at: <http://www.clinicalpharmacology-ip.com/Default.aspx>. Accessed on September 7, 2022. Search term: ivermectin.
3. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2022. Available at: <http://online.factsandcomparisons.com/login.aspx?url=/index.aspx&q=>. Accessed on September 7, 2022. Search term: ivermectin.
4. Centers for Disease Control and Prevention. Parasites - Onchocerciasis (also known as river blindness). Available at: <https://www.cdc.gov/parasites/onchocerciasis/>. Accessed on September 7, 2022.
5. Centers for Disease Control and Prevention. Chapter 4. Travel-related infectious diseases. Available at: <https://wwwnc.cdc.gov/travel/yellowbook/2020/travel-related-infectious-diseases/strongyloidiasis>. Accessed on September 7, 2022.
6. Micromedex® (electronic version). IBM Watson Health, Greenwood Village, Colorado, USA. Available at: <https://www.micromedexsolutions.com/>. Accessed on September 7, 2022. Search term: ivermectin.
7. Centers for Disease Control and Prevention. Parasites – Ascariasis. Available at: <https://www.cdc.gov/parasites/ascariasis/index.html>. Accessed on September 7, 2022.
8. Centers for Disease Control and Prevention. Parasites – Gnathostomiasis. Available at: https://www.cdc.gov/parasites/gnathostoma/health_professionals/index.htm. Accessed on September 7, 2022.
9. Centers for Disease Control and Prevention. Parasites – Zoonotic Hookworm. Available at: https://www.cdc.gov/parasites/zoonotichookworm/health_professionals/index.html#tx. Accessed on September 7, 2022.
10. Centers for Disease Control and Prevention. Parasites – Head Lice. Available at: <https://www.cdc.gov/parasites/lice/head/index.html>. Accessed on September 7, 2022.
11. Centers for Disease Control and Prevention. Parasites – Body Lice. Available at: <https://www.cdc.gov/parasites/lice/body/treatment.html>. Accessed on September 7, 2022.
12. Centers for Disease Control and Prevention. Parasites – Pubic “Crab” Lice. Available at: <https://www.cdc.gov/parasites/lice/pubic/index.html>. Accessed on September 7, 2022.
13. Centers for Disease Control and Prevention. Parasites – Scabies. Available at: <https://www.cdc.gov/parasites/scabies/index.html>. Accessed on September 7, 2022.
14. Centers for Disease Control and Prevention. Parasites – Trichuriasis (also known as whipworm infection). Available at: https://www.cdc.gov/parasites/whipworm/health_professionals/index.html. Accessed on September 7, 2022.
15. Centers for Disease Control and Prevention. Parasites – Lymphatic filariasis. Available at: <https://www.cdc.gov/parasites/lymphaticfilariasis/>. Accessed on September 7, 2022.
16. Ta-Ting TH, Crainey JL, Post RJ, et al. Mansonellosis: current perspectives. *Res Rep Trop Med*. 2018;9:9-24.
17. Centers for Disease Control and Prevention – COVID-19 Treatment Guidelines – Ivermectin. Last updated April 29, 2022. Available at: <https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/>. Accessed on September 9, 2022.