MEDICAL MUTUAL®

# Drug Policy

| Policy: | Ivermectin Tablets Prior Authorization<br>Stromectol® (ivermectin tablets-Merck,generic) | Annual Review Date:<br>10/19/2023<br><br>Last Revised Date:<br>10/19/2023 |
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## 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*, *Mansonella ozzardi* and *M. streptocerca* infections.[6,16]

## POLICY STATEMENT

This policy involves the use of ivermectin. Prior authorization is recommended for pharmacy benefit coverage of ivermectin. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis. All approvals are provided for 30 days, which is an adequate duration for the patient to receive the required number of doses.

**Automation:** When available, the following ICD-10 codes will be used for automation to allow approval of the requested medication: B73.*; B74.*; B76.*; B77.*; B78.*; B79; B80; B83.1; B85.*; B86

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of ivermectin is recommended in those who meet 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.

**Initial Approval/ Extended Approval.**
30 days (an adequate duration to receive the required number of doses)

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Ivermectin has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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.

**Documentation Requirements:**

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

## REFERENCES

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