PRIOR AUTHORIZATION POLICY

POLICY: Infectious Disease – Ivermectin Tablets Prior Authorization Policy
- Stromectol® (ivermectin tablets – Merck, generic)

REVIEW DATE: 02/28/2024

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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

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.

- **Stromectol® (ivermectin tablets (Merck, generic)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

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 COVERED

- **Stromectol® (ivermectin tablets (Merck, generic)**

is(are) considered experimental, investigational or unproven for ANY other use(s) including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

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.

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: https://www.clinicalkey.com/pharmacology/. Accessed on February 23, 2024. Search term: ivermectin.
3. Facts and Comparisons® Online. Wolters Kluwer Health, Inc.; 2024. Available at: http://fco.factsandcomparisons.com/lco/action/home. Accessed on February 23, 2024. 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 February 23, 2024.
5. 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.
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 February 23, 2024.
8. Centers for Disease Control and Prevention. Parasites – Gnathostomiasis. Available at: https://www.cdc.gov/parasites/gnathostoma/health_professionals. Accessed on February 23, 2024.
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 February 23, 2024.

10. Centers for Disease Control and Prevention. Parasites – Head Lice. Available at: https://www.cdc.gov/parasites/lice/head/index.html. 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: https://www.cdc.gov/parasites/lice/pubic/index.html. Accessed on February 23, 2024.
13. Centers for Disease Control and Prevention. Parasites – Scabies. Available at: https://www.cdc.gov/parasites/scabies/index.html. Accessed on February 23, 2024.
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 February 23, 2024.
15. Centers for Disease Control and Prevention. Parasites – Lymphatic filariasis. Available at: https://www.cdc.gov/parasites/lymphaticfilariasis/. 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.
17. Centers for Disease Control and Prevention – COVID-19 Treatment Guidelines – Ivermectin. Last updated December 20, 2023. Available at: https://www.covid19treatmentguidelines.nih.gov/therapies/antiviral-therapy/ivermectin/. Accessed on February 23, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes	09/13/2023
Early Annual Revision	For all indications, the number of approvable doses was removed. All approval durations remain for one month.	02/28/2024