Clinical Guideline



Oscar Clinical Guideline: Emverm (mebendazole) (PG001, Ver. 7)

Emverm (mebendazole)

Disclaimer

Clinical guidelines are developed and adopted to establish evidence-based clinical criteria for utilization management decisions. Clinical guidelines are applicable according to policy and plan type. The Plan may delegate utilization management decisions of certain services to third parties who may develop and adopt their own clinical criteria.

Coverage of services is subject to the terms, conditions, and limitations of a member's policy, as well as applicable state and federal law. Clinical guidelines are also subject to in-force criteria such as the Centers for Medicare & Medicaid Services (CMS) national coverage determination (NCD) or local coverage determination (LCD) for Medicare Advantage plans. Please refer to the member's policy documents (e.g., Certificate/Evidence of Coverage, Schedule of Benefits, Plan Formulary) or contact the Plan to confirm coverage.

Summary

Emverm (mebendazole) is an antihelminthic medication used to treat various types of parasitic worm infections such as ascariasis, enterobiasis, hookworm infections, trichuriasis, angiostrongyliasis, baylisascariasis, capillariasis, toxocariasis, trichinellosis, and trichostrongyliasis. It functions by selectively and irreversibly blocking glucose uptake and other nutrients in susceptible adult intestine-dwelling helminths, leading to their eventual death and expulsion from the body. The medication is consumed as an oral chewable tablet, with dosage and duration varying based on the specific parasitic infection being treated.

Definitions

"Antihelminthic" refers to a class of medications that work against parasitic worms (helminths), expelling them from the body.

"Ascariasis," "Enterobiasis," "Hookworm Infections," "Trichuriasis," "Angiostrongyliasis," "Baylisascariasis," "Capillariasis," "Toxocariasis," "Trichinellosis," and "Trichostrongyliasis" are all different types of parasitic worm infections for which mebendazole is a recommended treatment.

"Helminths" are parasitic worms, which can infest various parts of the body, causing a range of health problems.

"Microtubules" are components of a cell's structure that help maintain its shape and integrity. In helminths, these microtubules are disrupted by mebendazole, leading to the parasites' death.

"Nematodes" refer to a type of helminth, commonly known as roundworms, that mebendazole can effectively treat.

Medical Necessity Criteria for Initial Authorization

The Plan considers <u>Emverm (mebendazole)</u> medically necessary when ONE (1) of the following criteria is met:

- 1. The member has a documented diagnosis of ONE (1) of the following:
 - a. Alveolar echinococcosis; or
 - b. Ascariasis caused by Ascaris lumbricoides (roundworm); or
 - c. Baylisascariasis caused by Baylisascaris procyonis (raccoon roundworm); or
 - d. Capillariasis caused by Capillaria philippinensis (Philippine threadworm); or
 - e. Cystic echinococcosis (hydatid cyst disease); or
 - f. Eosinophilic enterocolitis caused by Ancylostoma caninum (dog hookworm); or
 - g. Eosinophilic meningitis caused by Angiostrongylus cantonensis; or
 - h. Toxocariasis (visceral larva migrans) caused by Toxocara canis or T. cati (dog or cat roundworm); *or*
 - i. Trichinellosis (trichinosis) caused by Trichinella spiralis (pork worm); or
 - j. Trichuriasis caused by Trichuris trichiura (whipworm); OR
- 2. The member has BOTH of the following:
 - a. A documented diagnosis of:
 - i. Enterobiasis caused by Enterobius vermicularis (pinworm); or
 - ii. Intestinal hookworm infections caused by Ancylostoma duodenale or Necator americanus in single or mixed infections; or
 - iii. Trichostrongyliasis caused by Trichostrongylus; AND
 - b. The member is unable to use, or has tried and failed over-the-counter (OTC) pyrantel pamoate.

If the above prior authorization criteria are met, Emverm (mebendazole) will be approved for up to 1 month. Prior Authorization may be extended based on the documentation provided, current treatment guidelines, and individual member needs (see Appendix A).

Medical Necessity Criteria for Reauthorization

All prior authorization renewals will be reviewed on a case-by-case basis to determine if continuation of therapy is medically necessary. The following should be provided for reauthorization:

- 1. Current clinical documentation supporting the need for continued therapy; AND
- 2. Response to the previous course of treatment; AND
- 3. Plan for the duration of continued treatment.

Prior Authorization may be extended based on the documentation provided, current treatment guidelines, and individual member needs (see Appendix A).

Experimental or Investigational / Not Medically Necessary

Emverm (mebendazole) for any other indication is considered not medically necessary by the Plan, as it is deemed to be experimental, investigational, or unproven.

References

- 1. Boreham RE, McCowan MJ, Ryan AE, Allworth AM, Robson JM. Human trichostrongyliasis in Queensland. Pathology. 1995 Apr;27(2):182-5. doi: 10.1080/00313029500169842.
- 2. Centers for Disease Control and Prevention (CDC). Parasites. 2024. Available at https://www.cdc.gov/parasites/index.html.
- 3. Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier Inc.: 2022. Available from: www.clinicalpharmacology.com. Updated periodically. Accessed: April 2022.
- 4. Drugs for Parasitic Infections, 3rd ed, The Medical Letter, New Rochelle, NY. 2013.
- 5. Emverm (mebendazole) [prescribing information]. Bridgewater, NJ: Amneal Specialty; January 2019.
- 6. Emverm (mebendazole) [prescribing information]. Wilmington, NC: Alcami; August 2021.
- 7. Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.: 2022. Available from: http://online.lexi.com. Updated periodically. Accessed: April 2022.
- 8. American Academy of Pediatrics (AAP). In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. Red Book: 2021-2024 Report of the Committee on Infectious Diseases. 32nd ed. American Academy of Pediatrics; 2021.
- 9. Vermox (mebendazole) [prescribing information]. Titusville, NJ: Janssen Pharmaceuticals Inc; September 2021.

Appendix A

Table 1: Dosage and Retreatment Information for Emverm (mebendazole) by Indication

| Indication | Dosage | Duration and Retreatment |
|---|--|---|
| Alveolar echinococcosis | Adults and children (2 to 17 years): 40-50 mg/kg orally daily. | 1 to 6 months for cystic disease and for at least 2 years in those being monitored for at least 10 years for alveolar disease. |
| Ascariasis caused by Ascaris lumbricoides (roundworm) | Adults and children: 500 mg orally | Single dose |
| | Adults and children: 100 mg orally twice daily | 3 days; if not cured 3 weeks after treatment, a second course of therapy is recommended |
| | Children 1 year: 100 mg orally twice daily | 3 days |
| Baylisascariasis caused by Baylisascaris procyonis (raccoon roundworm) | | |
| Capillariasis caused by Capillaria philippinensis (Philippine threadworm) | Adults and children (2 to 17 years): 200 mg orally twice daily | 20 days |
| Cystic echinococcosis (hydatid cyst disease) | Adults and children (2 to 17 years): 40-50 mg/kg orally daily. | 1 to 6 months for cystic disease and for at least 2 years in those being monitored for at least 10 years for alveolar disease. |
| Enterobiasis caused by Enterobius vermicularis (pinworm) | Adults and children (1 to 17 years): 100 mg orally | Single dose; repeat dose in 2 weeks |
| Eosinophilic enterocolitis caused by Ancylostoma caninum (dog hookworm) | Adults: 100 mg orally twice daily | 3 days |
| | Alternative dosing: 500 mg | Single-dose |
| Eosinophilic meningitis caused by Angiostrongylus cantonensis | Adults: 10 mg/kg orally daily | 14 days |

| Intestinal hookworm infections caused by Ancylostoma duodenale or Necator americanus in single or mixed infections | Adults and children: 500 mg orally | Single-dose |
|--|--|---|
| | Adults and children (1 to 17 years): 100 mg orally twice daily | 3 days; if not cured 3 weeks after treatment, a second course of therapy is recommended |
| Toxocariasis (visceral larva migrans) caused by Toxocara canis or T. cati (dog or cat roundworm) | Adults and children (2 to 17 years): 100-200 mg orally twice daily | 5 days |
| Trichinellosis (trichinosis) caused by Trichinella spiralis (pork worm) | Adults and children (2 to 17 years): 200-400 mg orally three times daily for 3 days, then 400-500 mg three times daily for 10 days | Total duration of 13 days |
| Trichuriasis caused by Trichuris trichiura (whipworm) | Adults and children: 500 mg orally | Single-dose |
| | Adults and children (2 to 17 years): 100 mg orally twice daily | 3 days; if not cured 3 weeks after treatment, a second course of therapy is recommended |
| | Children 1 year: 100 mg orally twice daily | 3 days |
| Trichostrongyliasis caused by Trichostrongylus | Adults: 100 mg orally twice daily | 3 days |

Clinical Guideline Revision / History Information

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