

Policy and Procedure

PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCINF030.1225	ANTI-INFECTIVE AGENTS ALBENDAZOLE (chewable tablet) EMVERM® (mebendazole chewable tablet)
Effective Date: 3/1/2026	Review/Revised Date: 04/16, 10/16, 10/17, 10/18, 10/19, 10/20, 10/21, 10/22, 11/23, 11/24, 10/25 (MTW)
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Approved by: Oregon Region Pharmacy and Therapeutics Committee	

SCOPE:

Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

APPLIES TO:

Commercial
Medicaid

POLICY CRITERIA:

COVERED USES:

All Medically Accepted indications not otherwise excluded from the benefit.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services when all applicable indication-specific criteria below are met or if the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit applies.

REQUIRED MEDICAL INFORMATION:

Coverage requires both of the following:

1. One of the following:
 - a. For the treatment of pinworms (*Enterobius vermicularis*):
 - i. Documentation of trial and failure, intolerance, or contraindication to pyrantel pamoate (available over the counter)
 - b. For diagnoses other than pinworm (*Enterobius vermicularis*):
 - i. Must be FDA approved or be a medically accepted indication (such as guideline directed therapy or compendia supported as listed in either the American Hospital Formulary System, Lexi-Drugs or Drugdex)
 - ii. Diagnosis of parasite species must be confirmed through validated laboratory testing/identification. If laboratory confirmation is not possible, must be prescribed by, or in consultation with, an infectious disease specialist

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2. For Emverm® requests: Documented trial and failure, intolerance, or contraindication to albendazole.

For quantity limit exception requests for Emverm®:

1. Medical rationale must be provided supporting use of the requested dose and/or duration of therapy.

EXCLUSION CRITERIA: N/A

AGE RESTRICTIONS: N/A

PRESCRIBER RESTRICTIONS:
See "Required Medical Information"

COVERAGE DURATION:
Authorization will be approved for three months.

QUANTITY LIMITS:

- Emverm®: 12 tablets per 30 days

Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.

Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.

Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.

Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.

INTRODUCTION:

Albendazole (Albenza®) and mebendazole (Emverm®) are anthelmintic agents. Albenza® is approved by the Food and Drug Administration (FDA) for the treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium* and cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus*.¹ Emverm® is FDA approved for the treatment of *Enterobius*

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vermicularis, (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm) in single or mixed infections.² Both medications have compendial support for multiple other indications.³

FDA APPROVED INDICATIONS:

Albenza® (albendazole):

- Parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium*
- Cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus*.

Emverm® (mebendazole):

- *Enterobius vermicularis*, (pinworm)
- *Trichuris trichiura* (whipworm)
- *Ascaris lumbricoides* (common roundworm)
- *Ancylostoma duodenale* (common hookworm)
- *Necator americanus* (American hookworm)

World Health Organization and CDC guidelines recommend use in several other parasitic infections.

POSITION STATEMENT:

- *Enterobius vermicularis* (pinworms) are the most common helminth infection in the United States.⁴
 - Pyrantel pamoate (ie. Pin-X or Reese's Pinworm Medicine) is available over the counter for the treatment of pinworms. It is indicated for adults and children 2 years of age and older; it is dosed at 11 mg/kg. Common side effects include diarrhea, nausea, vomiting, dizziness, headache, and somnolence.
 - Mebendazole (Emverm®) is FDA approved for the treatment of pinworms as a single dose of 100 mg. Common side effects include rash, abdominal pain, constipation, diarrhea, and headache.
 - Albendazole (Albenza®) is used off-label for the treatment of pinworms, as a single dose of 400 mg (two 200 mg tablets), repeated in 2 weeks. Common side effects include abdominal pain, nausea, vomiting, and headache.
- Intestinal parasites, neurocysticercosis, and hydatid disease is uncommon in the United States, with cases often occurring in immigrants and refugees.⁵

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- Albendazole has broad activity against helminths, with one review article indicating the following cure rates in various clinical trials: hookworm (78% in 68 studies), *A. duodenale* (92% in 23 studies), *N. americanus* (75% in 30 studies), *A. lumbricoides* (95% in 64 studies), *T. trichiura* (48% in 57 studies), *E. vermicularis* (98% in 27 studies), *S. stercoralis* (62% in 19 studies), *H. nana* (68% in 11 studies), and *Taenia spp.* (85% in 7 studies).⁶
- Albendazole was initially approved in 1996 and is now available in a generic product. Mebendazole production was discontinued in 2011, but a branded mebendazole product, Emverm®, was approved by the FDA in January of 2016.

Early and Periodic Screening Diagnostic and Treatment (EPSDT) Review

The Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefit includes comprehensive preventative health care services for Medicaid members until they turn age 21 and for members with qualifying special health care needs (Youth with Special Healthcare Needs (YSHCN)) as they turn 21. This benefit applies when a condition is determined to impact the ability to grow, develop or participate in school and the applicable criteria above are met.

REFERENCE/RESOURCES:

1. Albenza® (albendazole) package insert. Horsham, PA: Amedra Pharmaceuticals, LLC; 2019 September.
2. Emverm® (mebendazole) package insert. Horsham, PA: Amedra Pharmaceuticals, LLC; 2021 August.
3. Albendazole and mebendazole. In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically. (Accessed October 21, 2025).
4. Burkhard CN, Burkhart CG. Assessment of frequency, transmission, and genitourinary complications of enterobiasis (pinworms). *Int J Dermatol.* 2005;44(10):837-40.
5. Alpem JD, Stauffer WM, Kesselheim AS. High-cost generic drugs – implications for patients and policymakers. *N Engl J Med.* 2014;371:1859-1862.
6. Horton J. Albendazole: a review of anthelmintic efficacy and safety in humans. *Parasitology.* 2000;121 Suppl:S113-32.