



albendazole (Albenza)

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.

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Summary

Albendazole (Albenza) is a broad-spectrum antihelminthic medication primarily used in the treatment of various types of helminthic (parasitic worm) infections, such as roundworms, hookworms, pinworms, and whipworms. It is also approved for treatment of parenchymal neurocysticercosis and cystic hydatid disease of the liver, lung, peritoneum. Albendazole acts by inhibiting the formation of helminth microtubules, thereby blocking the uptake of glucose and other nutrients in susceptible adult intestine-dwelling helminths, which leads to their death. The drug is administered orally and the dose and duration of therapy are dependent on the specific type of parasitic infection being treated.

Definitions

"Anthelmintics" refer to a class of antiparasitic drugs that target and help eliminate parasitic worms and other internal parasites from the body.

"Documentation" refers to written information, including but not limited to:

- Up-to-date chart notes, relevant test results, and/or relevant imaging reports to support diagnoses; or
- Prescription claims records, and/or prescription receipts to support prior trials of formulary alternatives.

"Helminths" are a group of parasitic worms.

"Microtubules" are cylindrical structures within cellular cytoplasm that provide structure and shape to cells and are involved in many cellular processes including cell division and intracellular transport.

"[s]" indicates state mandates may apply.

Clinical Indications

Medical Necessity Criteria for Initial Clinical Review

Initial Indication-Specific Criteria

Infections

The Plan considers albendazole (Albenza) medically necessary when when ALL of the following criteria are met:

1. The member has ONE (1) of the following:
 - a. The member has a has a documented diagnosis of ONE (1) of the following:
 - i. Ascariasis caused by *Ascaris lumbricoides* (roundworm); *or*
 - ii. Baylisascariasis caused by *Baylisascaris procyonis* (raccoon roundworm); *or*
 - iii. Capillariasis caused by *Capillaria philippinensis* (Philippine threadworm); *or*

- iv. Cutaneous larva migrans (creeping eruption) caused by dog or cat hookworms; *or*
- v. Cystic hydatid disease (unilocular hydatid disease) of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm (*Echinococcus granulosus*); *or*
- vi. Eosinophilic enterocolitis caused by *Ancylostoma caninum* (dog hookworm); *or*
- vii. Filariasis caused by *Wuchereria bancrofti* or *Brugia malayi* (roundworms); *or*
- viii. Gnathostomiasis caused by *Gnathostoma spinigerum*; *or*
- ix. Gongylonemiasis caused by *Gongylonema*; *or*
- x. Intestinal hookworm infections caused by *Ancylostoma duodenale* or *Necator americanus*; *or*
- xi. Loiasis caused by *Loa loa* (roundworm); *or*
- xii. Microsporidiosis (intestinal microsporidiosis caused by *Encephalitozoon intestinalis*, ocular microsporidiosis, disseminated microsporidiosis caused by microsporidia other than *Enterocytozoon bieneusi* and *V. corneae*); *or*
- xiii. Oesophagostomiasis caused by *Oesophagostomum bifurcum*; *or*
- xiv. Parenchymal neurocysticercosis resulting from active lesions caused by *Cysticercus cellulosae*, the larval form of *Taenia solium* (pork tapeworm), parenchymal disease; *or*
- xv. Strongyloidiasis caused by *Strongyloides stercoralis* (threadworm); *or*
- xvi. Toxocariasis (visceral larva migrans) caused by *Toxocara canis* or *T. cati* (dog or cat roundworm); *or*
- xvii. Trematode (Fluke) infections caused by *Clonorchis sinensis* (Chinese liver fluke) or *Opisthorchis viverrini* (Southeast Asian liver fluke); *or*
- xviii. Trichinellosis (trichinosis) caused by *Trichinella spiralis* (pork worm); *or*
- xix. Trichuriasis caused by *Trichuris trichiura* (whipworm); *or*
- b. The member has **BOTH** of the following:
 - i. A documented diagnosis of:
 - 1. Enterobiasis caused by *Enterobius vermicularis* (pinworm); *or*
 - 2. Trichostrongylosis caused by *Trichostrongylus*; *and*
 - ii. The member is unable to use, or has tried and failed over-the-counter (OTC) pyrantel pamoate^[5]; *or*
- c. The member has **BOTH** of the following:
 - i. A documented diagnosis of giardiasis caused by *Giardia duodenalis* (also known as *G. lamblia* or *G. intestinalis*); *and*
 - ii. The member meets **ONE** (1) of the following:
 - 1. IF the member is 17 years of age or younger, unable to use, or has tried and failed **ONE** of the preferred alternatives^[5]:
 - a. metronidazole; *and*
 - b. nitazoxanide; *and*
 - c. tinidazole; *or*

2. IF The member is 18 years of age and older, unable to use, or has tried and failed ALL of the preferred alternatives^[s]:
 - a. metronidazole; *and*
 - b. nitazoxanide; *and*
 - c. tinidazole; *AND*
2. The following baseline tests have been completed before initiation of treatment as clinically appropriate:
 - a. Complete blood count (CBC); *and/or*
 - b. Pregnancy test in a woman of reproductive potential; *and/or*
 - c. Ophthalmic exam for retinal lesions before initiating therapy for neurocysticercosis; *AND*
3. IF the request is for brand Albenza, the member is unable to use, or has tried and failed generic albendazole from TWO manufacturers, when available^[s]; *AND*
4. Albendazole (Albenza) is being prescribed at a dose and frequency that is within FDA approved labeling OR is supported by compendia or evidence-based published dosing guidelines for the requested indication.

If the above prior authorization criteria is met, albendazole (Albenza) will be approved for ONE of the following:^[s]

- For up to 6 months for members with a diagnosis of:
 - cystic hydatid disease (Echinococcus granulosus, dog tapeworm); *or*
 - parenchymal neurocysticercosis (Taenia solium, pork tapeworm); *or*
- For up to 1 month members with all other diagnoses; *or*
- Prior Authorization may be extended based on the documentation provided, current treatment guidelines, and individual member needs

Continued Care

Medical Necessity Criteria for Subsequent Clinical Review

Subsequent Indication-Specific Criteria

Infections

The Plan considers albendazole (Albenza) medically necessary when the following criterion is met:

1. 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:
 - a. Current clinical documentation supporting the need for continued therapy; *and*
 - b. Response to the previous course of treatment; *and*
 - c. Plan for the duration of continued treatment.

Prior Authorization may be extended based on the documentation provided, current treatment guidelines, and individual member needs.^[s]

Experimental / Investigational, or unproven^[s]

albendazole (Albenza) for any other use is considered experimental, investigational, or unproven.

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Clinical Guideline Revision / History Information

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