# oscar

# **Clinical Guideline**

Oscar Clinical Guideline: albendazole (Albenza) (PG101, Ver. 5)

# 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.

#### 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. 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

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

"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.

#### Medical Necessity Criteria for Initial Authorization

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

- 1. **ONE** of the following:
  - a. The member has a has a documented diagnosis of **ONE** 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. loiasis caused by Loa loa (roundworm); or
    - xi. microsporidiosis (intestinal microsporidiosis caused by Encephalitozoon intestinalis, ocular microsporidiosis, disseminated microsporidiosis caused by microsporidia other than Enterocytozoon bieneusi and V. corneae); **or**
    - xii. parenchymal neurocysticercosis resulting from active lesions caused by Cysticercus cellulosae, the larval form of Taenia solium (pork tapeworm), parenchymal disease; **or**
    - xiii. strongyloidiasis caused by Strongyloides stercoralis (threadworm); or
    - xiv. toxocariasis (visceral larva migrans) caused by Toxocara canis or T. cati (dog or cat roundworm); or
    - xv. trematode (Fluke) infections caused by Clonorchis sinensis (Chinese liver fluke) or Opisthorchis viverrini (Southeast Asian liver fluke); **or**

- xvi. trichinellosis (trichinosis) caused by Trichinella spiralis (pork worm); or
- xvii. 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
    - intestinal hookworm infections caused by Ancylostoma duodenale or Necator americanus; or
    - 3. oesophagostomiasis caused by Oesophagostomum bifurcum; or
    - 4. trichostrongyliasis caused by Trichostrongylus; and
  - ii. tried and failed, or is unable to use over-the-counter pyrantel pamoate; 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. tried and failed, or is unable to use ALL of the preferred alternatives:
    - 1. metronidazole; or
    - 2. nitazoxanide; or
    - 3. tinidazole; AND
- 2. The following baseline tests have been completed before initiation of treatment as clinically appropriate:
  - a. complete blood count (CBC)
  - b. pregnancy test in a woman of reproductive potential
  - c. ophthalmic exam for retinal lesions before initiating therapy for neurocysticercosis; AND
- 3. Chart documentation and supporting lab work are provided for review to validate the abovelisted requirements.

If the above prior authorization criteria is met, albendazole (Albenza) will be approved:

- for 6 months for members with a diagnosis of:
  - cystic hydatid disease (Echinococcus granulosis, dog tapeworm); or
  - parenchymal neurocysticercosis (Taenia solium, pork tapeworm); or
- for 1 month members with all other documented diagnosis.

#### 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;
- 2. Response to the previous course of treatment;
- 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.

## Experimental or Investigational / Not Medically Necessary

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

## References

- 1. Albendazole tablets [prescribing information]. Piscataway, NJ: Camber Pharmaceuticals Inc; November 2022.
- 2. Albenza (albendazole) tablets [prescribing information]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; September 2019.
- American Academy of Pediatrics (AAP). In: Kimberlin DW, Brady MT, Jackson MA, Long SA, eds. Red Book: 2018 Report of the Committee on Infectious Diseases. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018.
- 4. Centers for Disease Control and Prevention (CDC). Parasites. 2024. Available at https://www.cdc.gov/parasites/index.html.
- 5. Centers for Disease Control and Prevention (CDC). Parasites. 2022. Available at https://www.cdc.gov/parasites/az/index.html
- 6. Clinical Pharmacology [database on the Internet]. Tampa (FL): Elsevier Inc.: 2022. Available from: www.clinicalpharmacology.com. Updated periodically. Accessed: April 2022.
- 7. Drugs for Parasitic Infections, 3rd ed, The Medical Letter, New Rochelle, NY. 2013.
- 8. Drugs for Parasitic Infections. Med Lett Drugs Ther. 2013. 11(suppl):e1-e31.
- Fryar CD, Carroll MD, Gu Q, Afful J, Ogden CL. Anthropometric reference data for children and adults: United States, 2015–2018. National Center for Health Statistics. Vital Health Stat 3(46). 2021.Available at: https://www.cdc.gov/nchs/data/series/sr\_03/sr03\_039.pdf. Accessed Sept 2021.
- 10. Lexicomp Online Database [database on the Internet]. Hudson (OH): Lexicomp Inc.: 2022. Available from: http://online.lexi.com. Updated periodically. Accessed: April 2022.
- 11. Micromedex (electronic version). IBM Watson Health, Greenwood Village, CO. Available at: https://www.micromedexsolutions.com. Accessed Sept 2021.

- Okumura N, Yamamoto K, Ohmagari N. Relapse of toxocariasis after completion of four-week treatment with albendazole. J Infect Chemother. 2024 Aug;30(8):796-799. doi: 10.1016/j.jiac.2024.01.010. Epub 2024 Jan 17. PMID: 38242286.
- 13. Persichino JG, Miller LG. Pregnancy screening and monitoring of albendazole therapy for neurocysticercosis. Clin Infect Dis. 2018;67(11):1797-1798.
- 14. White AC Jr, Coyle CM, Rajshekhar V, et al. Diagnosis and treatment of neurocysticercosis: 2017 Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA) and the American Society of Tropical Medicine and Hygiene (ASTMH). Clin Infect Dis. 2018;66(8):e49e75. doi: 10.1093/cid/cix1084.
- 15. World Health Organization (WHO). WHO guidelines on management of Taenia solium neurocysticercosis. Geneva: World Health Organization; 2021.

## Clinical Guideline Revision / History Information

Original Date: 10/14/2021 <u>Reviewed/Revised:</u> 12/01/2021, 06/23/2022, 06/29/2023, **12/19/2024**