

5.01.42

| | | | |
|--------------------|-----------------------|------------------------------|---------------|
| Section: | Prescription Drugs | Effective Date: | April 1, 2021 |
| Subsection: | Anti-Infective Agents | Original Policy Date: | March 3, 2017 |
| Subject: | Anthelmintic Drugs | Page: | 1 of 5 |

Last Review Date: March 12, 2021

Anthelmintic Drugs

Description

Albenza (albendazole), Egaten* (triclabendazole), Emverm (mebendazole)

*This medication is included in this policy but is not available in the market as of yet

Background

Anthelmintics are agents used to eliminate intestinal worms (helminthes) from the body. Helminthes can be divided into three groups: cestodes, or tapeworms; nematodes, or roundworms; and trematodes, or flukes. The helminthes differ from other infectious organisms in that they have a complex body structure. They are multicellular and have partial or complete organ systems (e.g., muscular, nervous, digestive, and reproductive). Several of the drugs used to treat worm infections affect the nervous system of the parasite and result in muscle paralysis. Other drugs affect the uptake of glucose and thus energy stores. Anthelmintics are effective in eradicating worms but proper hygiene is necessary to prevent re-infection (1).

Regulatory Status

FDA-approved indication:

1. Albenza is an anthelmintic drug indicated for: (2)
 - a. Treatment of parenchymal neurocysticercosis due to active lesions caused by larval forms of the pork tapeworm, *Taenia solium*.
 - b. Treatment of cystic hydatid disease of the liver, lung, and peritoneum, caused by the larval form of the dog tapeworm, *Echinococcus granulosus*.
2. Emverm is an anthelmintic drug indicated for the treatment of *Enterobius vermicularis* (pinworm), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm),

| | | | |
|--------------------|-----------------------|------------------------------|---------------|
| Section: | Prescription Drugs | Effective Date: | April 1, 2021 |
| Subsection: | Anti-Infective Agents | Original Policy Date: | March 3, 2017 |
| Subject: | Anthelmintic Drugs | Page: | 2 of 5 |

Ancylostoma duodenale (common hookworm), and *Necator americanus* (American hookworm) in single or mixed infections (3).

3. Egaten is an anthelmintic indicated for the treatment of fascioliasis (4).

World Health Organization and CDC guidelines recommend use in several other parasitic infections (1).

Related policies

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Anthelmintic drugs may be considered **medically necessary** for the treatment of *Enterobius vermicularis* (pinworm) with an inadequate response, intolerance, or contraindication to over-the-counter pyrantel pamoate (Pin-X, Pinworm suspension), *Trichuris trichiura* (whipworm), *Ascaris lumbricoides* (common roundworm), *Ancylostoma duodenale* (common hookworm), *Necator americanus* (American hookworm), *Strongyloides stercoralis* (threadworm), *Dracunculus medinensis* (guinea worm), *Onchocerca volvulus* (filarial worm), *Echinococcus granulosus* (dog tapeworm), *Taenia saginata* (beef tapeworm), *Taenia solium* (pork tapeworm), *Fasciola hepatica* (liver fluke), or *Schistosoma* spp. (blood fluke).

Anthelmintic drugs may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. *Enterobius vermicularis* (pinworm)
 - a. Inadequate response, intolerance, or contraindication to over-the-counter pyrantel pamoate (Pin-X, Pinworm suspension)
2. *Trichuris trichiura* (whipworm)
3. *Ascaris lumbricoides* (common roundworm)
4. *Ancylostoma duodenale* (common hookworm)
5. *Necator americanus* (American hookworm)

| | | | |
|--------------------|-----------------------|------------------------------|---------------|
| Section: | Prescription Drugs | Effective Date: | April 1, 2021 |
| Subsection: | Anti-Infective Agents | Original Policy Date: | March 3, 2017 |
| Subject: | Anthelmintic Drugs | Page: | 3 of 5 |

6. *Strongyloides stercoralis* (threadworm)
7. *Dracunculus medinensis* (guinea worm)
8. *Onchocerca volvulus* (filarial worm)
9. *Echinococcus granulosus* (dog tapeworm)
10. *Taenia saginata* (beef tapeworm)
11. *Taenia solium* (pork tapeworm)
12. *Fasciola hepatica* (liver fluke)
13. *Schistosoma spp* (blood fluke)

AND the following for Egaten requests **only**:

1. Prescriber will be dosing the patient within the FDA labeled dose of up to 20 mg/kg/day

Prior – Approval *Renewal* Requirements

Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

| | | |
|-----------------|---|------------------------------------|
| Quantity | Emverm | 12 tablets OR |
| | Albenza | 120 tablets per 30 days OR |
| | Egaten | Maximum daily dose of 20 mg/kg/day |
| Duration | <i>Enterobius vermicularis</i> (pinworm) | 1 month |
| | Other indications | 6 months |

Prior – Approval *Renewal* Limits

Same as above

The Service Benefit Plan's maximum benefit is 1 cycle of Anthelmintic therapy per 12 month period.

| | | | |
|--------------------|-----------------------|------------------------------|---------------|
| Section: | Prescription Drugs | Effective Date: | April 1, 2021 |
| Subsection: | Anti-Infective Agents | Original Policy Date: | March 3, 2017 |
| Subject: | Anthelmintic Drugs | Page: | 4 of 5 |

Rationale

Summary

Anthelmintics are agents used to eliminate intestinal worms (helminthes) from the body. Several of the drugs used to treat worm infections affect the nervous system of the parasite and result in muscle paralysis. Other drugs affect the uptake of glucose and thus energy stores. Both Emverm and Albenza are indicated for the treatment of various types of helminthes.

Anthelmintics are effective in eradicating worms but proper hygiene is necessary to prevent re-infection (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Anthelmintic drugs while maintaining optimal therapeutic outcomes.

References

1. World Health Organization. Preventive chemotherapy in human helminthiasis: a manual for health professionals. 2006.
2. Albenza [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; June 2019.
3. Emverm [package insert]. Bridgewater, NJ: Amneal Pharmaceuticals LLC; January 2019.
4. Egaten [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019.

Policy History

| Date | Action |
|---------------|---|
| March 2017 | New addition to PA |
| June 2017 | Annual review |
| December 2017 | Annual review and reference update |
| November 2018 | Annual review and reference update |
| March 2019 | Addition of Egaten. Added renewal requirements and "The Service Benefit Plan's maximum benefit is 1 cycle of Anthelmintic therapy per 12 month period." |
| June 2019 | Annual review |
| December 2019 | Annual review and reference update |
| December 2020 | Annual review and reference update |
| March 2021 | Annual review |

Keywords

5.01.42

Section: Prescription Drugs

Effective Date: April 1, 2021

Subsection: Anti-Infective Agents

Original Policy Date: March 3, 2017

Subject: Anthelmintic Drugs

Page: 5 of 5

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.