Clinical Policy: Triclabendazole (Egaten)

Reference Number: PA.CP.PMN.207
Effective Date: 01/2020
Last Review Date: 07/2023

Revision Log

Description
Triclabendazole (Egaten™) is an anthelmintic agent.

FDA Approved Indication(s)
Egaten is indicated for the treatment of fascioliasis in patients 6 years of age and older.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Egaten is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Fascioliasis (must meet all)**:**

1. Diagnosis of fascioliasis;
2. Prescribed by or in consultation with an infectious disease specialist or gastroenterologist;
3. Age ≥ 6 years;
4. Dose does not exceed 10 mg/kg per dose for 2 doses.

Approval duration: 4 weeks (no more than 2 total doses)

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Fascioliasis

1. Re-authorization is not permitted. Members must meet the initial approval criteria for new cases of fascioliasis unrelated to the original medication request.

Approval duration: Not applicable

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives
Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): known hypersensitivity to triclabendazole, other benzimidazole derivatives, or any of the excipients of Egaten
- Boxed warning(s): none reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Fascioliasis	Two doses of 10 mg/kg PO 12 hours apart*	Two doses of 10 mg/kg

*The 250 mg tablets are functionally scored and divisible into two equal halves of 125 mg. If the dosage cannot be adjusted exactly, round the dose upwards.

VI. Product Availability

Tablets: 250 mg

VII. References

1. Egaten Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; February 2022. Available at https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/208711s002lbl.pdf.. Accessed April 20, 2023.
2. Clinical Pharmacology [database online]. Elsevier, Inc.; 2022. Available at: https://www.clinicalkey.com/pharmacology/. Accessed April 20, 2023.
3. Hien TT, et al. A randomized controlled pilot study of artesunate versus triclabendazole for human fascioliasis in central Vietnam. Am J Trop Med Hyg. 2008;78(3):388-392.
4. Centers for Disease Control and Prevention. Parasites: Fasciola. Available at: https://www.cdc.gov/parasites/fasciola/health_professionals/index.html. Updated September 16, 2020. Accessed April 20, 2023.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01/2020	
3Q 2020 annual review: references reviewed and updated.	07/2020	
3Q 2021 annual review: no significant changes; references reviewed and updated.	07/2021	

Reviews, Revisions, and Approvals	Date	P&T Approval Date
3Q 2022 annual review: no significant changes; references reviewed and updated.	07/2022	
3Q 2023 annual review: no significant changes; references reviewed and updated.	07/2023	