Clinical Policy: Triclabendazole (Egaten)

Reference Number: ERX.NPA.120
Effective Date: 09.01.19
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ 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 ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 policy – ERX.PA.01 or evidence of coverage documents.

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

VI. Product Availability

Tablet: 250 mg

VII. References

1. Egaten Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; December 2020. Available at https://dailymed.nlm.nih.gov/dailymed. Accessed May 3, 2021.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2021. Available at: http://www.clinicalpharmacology-ip.com/.
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 May 3, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	04.02.19	08.19
3Q 2020 annual review: no significant changes; references reviewed and updated.	04.29.20	08.20
3Q 2021 annual review: no significant changes; references reviewed and updated.	05.03.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.