Clinical Policy Title:	triclabendazole
Policy Number:	RxA.110
Drug(s) Applied:	Egaten™
Original Policy Date:	02/07/2020
Last Review Date:	03/09/2021
Line of Business Policy Applies to:	All Line of Business

Background

Triclabendazole (Egaten™) is an anthelmintic agent indicated for the treatment of fascioliasis in patients 6 years of age and older.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
triclabendazole (Egaten™)	Fascioliasis	Two doses of 10 mg/kg PO 12 hours apart*	20 mg/kg/day

*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.

Dosage Forms

- Tablets: 250 mg, functionally scored

Clinical Policy

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

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 of age or older;
4. Dose does not exceed 10 mg/kg per dose for 2 doses.

Approval Duration

Commercial: 4 weeks (no more than 2 total doses)

Medicaid: 4 weeks (no more than 2 total doses)

II. Continued Therapy Approval

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
Commercial: Not applicable
Medicaid: Not applicable

III. Appendices

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

APPENDIX D: General Information
Monitor ECG in patients with a history of QT prolongation or who are taking medications which prolong the QT interval.

References

1. Egaten Prescribing Information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; September 2019. Available at https://dailymed.nlm.nih.gov/dailymed/fda/fdaDrugXsl.cfm?setid=5552884e-10ea-450c-9658-d3d4f33c946e&type=display. Accessed January 18, 2021.
2. Egaten Drug Monograph. Clinical Pharmacology. Accessed January 18, 2021. 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. Accessed January 18, 2021.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	02/07/2020
Updated references	04/28/2020	05/20/2020
Policy was reviewed. 1. Policy title table was updated. 2. Line of business policy applies was updated to All lines of business. 3. Approval duration updated for Initial and Continued 4. Appendix D: General Information added - Monitor ECG in patients with a history of QT prolongation or who are taking medications which prolong the QT interval. 5. References were reviewed and	01/18/2021	03/09/2021

updated. 6. Dosage Form update to add functionally scored 7. Maximum Dose updated to:20 mg/kg/day		