## Triclabendazole

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### Related Coverage Resources

**INSTRUCTIONS FOR USE**

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer’s particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer’s benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer’s benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

### Medical Necessity Criteria

Triclabendazole (Egaten™) is medically necessary when the following criteria is met:

- Treatment of fascioliasis

Authorization is for one treatment course only.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Triclabendazole is considered experimental, investigational or unproven for ANY other use.

Note: Receipt of sample product does not satisfy any criteria requirements for coverage.

### FDA Approved Indications

**FDA Approved Indication**

Egaten™ is indicated for the treatment of fascioliasis in patients 6 years of age and older.
**Recommended Dosing**

**FDA Recommended Dosing**
The recommended dose of Egaten is 2 doses of 10 mg/kg given 12 hours apart in patients 6 years of age and older. 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.

Take Egaten orally with food. Egaten tablets can be swallowed whole or divided in half and taken with water or crushed and administered with applesauce. The crushed tablet mixed with applesauce is stable for up to 4 hours.

**Drug Availability**
Supplied as functionally scored tablets containing 250 mg of triclabendazole.

Novartis has been donating Egaten to World Health Organization (WHO) since 2005 and will continue to do so through 2022. (Novartis, 2019) Egaten is distributed from manufacturer to pharmacy. Healthcare professionals can find information on obtaining a donation of triclabendazole at:
https://www.who.int/foodborne_trematode_infections/fascioliasis/fascioliasis_partnership/en/

**Background**

**Disease Overview**
Fascioliasis is an infectious parasitic disease caused by Fasciola parasites, which are flat worms known as liver flukes (nematodes). Fascioliasis is not endemic in the US, although there are cases of fascioliasis, mainly in immigrants or travelers who were infected in countries where fascioliasis is well known to occur. The World Health Organization (WHO) estimates that at least 2.4 million people are infected worldwide. Patients become infected by eating raw watercress or other water plants or by drinking water contaminated with immature larvae. Clinical symptoms during the acute phase include fever, nausea, a swollen liver, skin rashes, and severe abdominal pain. Clinical manifestations associated with chronic infection include pain, anemia, pancreatitis, gallstones, fibrosis, and bacterial-super infections.

**Professional Societies/Organizations**
The World Health Organization (WHO) considers Egaten the drug of choice for treatment of fascioliasis. (CDC, 2019; WHO 2019) Alinia is not mentioned by the WHO. Egaten is recognized by the CDC as the drug of choice for this condition (2019). Prior to FDA approval, Egaten was available through the CDC under a special protocol. (CDC, 2019) The CDC mentions that Alinia might be effective for some patients based on limited data. Therefore, it is a potential alternative to Egaten for fascioliasis. Novartis has been donating Egaten to the WHO since 2005 and will continue to do so through 2022. (Press, 2019)

**Comparative Studies**
The efficacy of Egaten was supported by one pivotal, open-label, randomized study conducted in Vietnam, in which Egaten was compared with oral artesunate (not available in the US) in patients with acute symptomatic fascioliasis. (Egaten, 2019)

Eligible patients were > 8 years of age who met the case definition for fascioliasis, defined as having all of the following: clinical symptoms consistent with fascioliasis (including but not limited to abdominal pain, fever, itch, urticarial rash, jaundice); ultrasound scan of the liver consistent with human fascioliasis; positive Fasciola serology (using an enzyme linked immunosorbent assay [ELISA]); eosinophilia > 400,000 cells/mL; and living in an endemic area for fascioliasis. (Egaten, 2019)

100 patients were randomized 1:1 to either two doses of triclabendazole (10 mg/kg/dose, given 12 hours apart with food) or artesunate (4 mg/kg/day once daily [QD] for 10 days). (Hien, 2008) All patients were treated in the hospital and were observed for 10 days. Complete blood count, including absolute eosinophil count and percentage, alanine aminotransferase, aspartate aminotransferase, serology using a *Fasciola*-specific ELISA,
and liver ultrasound scan were performed at study entry, hospital discharge, and 3 months post-treatment. The efficacy endpoints were evaluated using the intent-to-treat (ITT) and per-protocol (PP) populations.

The primary efficacy endpoint was resolution of abdominal pain at hospital discharge (Day 10). (Hien, 2008) The key secondary endpoint was the complete response rate at 3 months post-treatment, defined as resolution of symptoms, normalization of eosinophil count, and improvement in the ultrasound scans.

At hospital discharge, significantly more patients in the artesunate group (100%) achieved the primary endpoint of resolution of abdominal pain compared with triclabendazole (88%) \( P = 0.027 \). However, significantly more patients in the triclabendazole group (36%) achieved the key secondary endpoint, complete response, compared with artesunate (10%) in the ITT analysis. The relative risk was 0.28 (95% CI: 0.11, 0.690; \( P = 0.004 \)). The findings were similar for the per-protocol (PP) population. (Hien, 2008)

### References