



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1242-7
Program	Prior Authorization - Notification
Medication	Benznidazole
P&T Approval Date	3/2018, 3/2019, 3/2020, 3/2021, 3/2022, 3/2023, 3/2024
Effective Date	6/1/2024

1. Background:

Benznidazole, a nitroimidazole antimicrobial, is indicated in pediatric patients 2 to 12 years of age for the treatment of Chagas disease (American trypanosomiasis), caused by *Trypanosoma cruzi*.¹

This indication is approved under accelerated approval based on the number of treated patients who became Immunoglobulin G (IgG) antibody negative against the recombinant antigens of *T. cruzi*. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Antiparasitic treatment is indicated for all cases of acute or reactivated Chagas disease and for chronic *Trypanosoma cruzi* (*T. cruzi*) infection in children up to 18 years old. Congenital infections are considered acute disease. Treatment is strongly recommended for adults up to 50 years old with chronic infection who do not already have advanced Chagas cardiomyopathy. For adults older than 50 years with chronic *T. cruzi* infection, the decision to treat with antiparasitic drugs should be individualized, weighing the potential benefits and risks for the patient. Physicians should consider factors such as the patient's age, clinical status, preference, and overall health.²

2. Coverage Criteria^a:

A. Authorization

1. Benznidazole will be approved based on the following criteria:

a. Diagnosis of Chagas disease (American trypanosomiasis) due to *Trypanosoma cruzi*

Authorization will be issued for 60 days.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Benznidazole [package insert]. Florham Park, NJ: Exeltis USA, Inc.: September 2021.
2. CDC Guidelines. Parasites – American Trypanosomiasis (also known as Chagas Disease). <https://www.cdc.gov/parasites/chagas/>. Accessed January 2023.

Program	Prior Authorization - Benznidazole
Change Control	
Date	Change
3/2018	New program.
3/2019	Annual review. Added statement regarding use of automated process.
3/2020	Annual review. Updated references.
3/2021	Annual review. No changes.
3/2022	Annual review. Updated references.
3/2023	Annual review. Added mandate language.
3/2024	Annual review. No changes.