Pharmacy Policy Bulletin: J-0678 Drugs for Chagas Disease – Commercial and Healthcare Reform	
Number: J-0678	**Category:** Prior Authorization
Line(s) of Business: ☒ Commercial ☒ Healthcare Reform ☐ Medicare	**Benefit(s):** **Commercial:** **Prior Authorization (1.):** **1.** Other Managed Prior Authorization = Yes w/ Prior Authorization **Healthcare Reform:** Not Applicable
Region(s): ☒ All ☐ Delaware ☐ New York ☐ Pennsylvania ☐ West Virginia	**Additional Restriction(s):** None
Version: J-0678-009	**Original Date:** 11/08/2017
Effective Date: 10/28/2024	**Review Date:** 10/02/2024

Drugs Product(s):	• benznidazole • Lampit (nifurtimox)

FDA-Approved Indication(s):	• benznidazole
	  ○ Treatment of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi* in pediatric patients 2 to 12 years of age
	• Lampit (nifurtimox)
	  ○ Treatment of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi* in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg)

Background:	• Chagas disease, also known as American trypanosomiasis, is caused by the parasite *Trypanosoma cruzi* (*T. cruzi*). The major manifestations of Chagas disease are Chagas cardiomyopathy and gastrointestinal disease. • Benznidazole exhibits antimicrobial activity via inhibition of DNA, RNA and protein synthesis within the *T. cruzi* parasite, although the exact mechanism of action is unknown. • The mechanism of action of Lampit is unknown, but it is suggested that toxic metabolites of the drug cause DNA damage and cell death of intracellular and extracellular *T. cruzi.* • The Centers for Disease Control and Prevention (CDC) recommends treatment for all cases of acute or reactivated Chagas disease and for chronic *T. cruzi* infection in children up to age 18. Treatment is also strongly recommended for adults up to 50 years of age with chronic infection who do not already have advanced cardiomyopathy. For patients who are older than 50 years of age with chronic *T.* cruzi infection, the decision to treat with antiparasitic drugs should be individualized, weighing potential benefits and risks for the patient. Both benznidazole and nifurtimox are recommended in the treatment of Chagas disease. • Prescribing considerations: ○ Treatment with Lampit and benznidazole should be administered for 60 days.

	○ Lampit and benznidazole have warnings and precautions for genotoxicity and carcinogenicity, hypersensitivity reactions, and embryo-fetal toxicity. Lampit has additional warnings and precautions for worsening of neurological and psychiatric conditions, decreased appetite and weight loss, and porphyria. Benznidazole has additional warnings and precautions for paresthesia/peripheral neuropathy and hematological manifestations of bone marrow depression.

Approval Criteria

I. Approval Criteria

A. benznidazole

When a benefit, coverage of benznidazole may be approved when all of the following criteria are met **(1. and 2.)**:

1. The member is 2 years of age or older.

2. The member has a diagnosis of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi*. (ICD-10: B57)

B. Lampit

When a benefit, coverage of Lampit may be approved when all of the following criteria are met **(1. and 2.):**

1. The member weighs at least 2.5 kg.

2. The member has a diagnosis of Chagas disease (American trypanosomiasis) caused by *Trypanosoma cruzi*. (ICD-10: B57)

II. An exception to some or all of the criteria above may be granted for select members and/or circumstances based on state and/or federal regulations.

Limitations of Coverage

I. Coverage of drug(s) addressed in this policy for disease states outside of the FDA-approved indications should be denied based on the lack of clinical data to support their effectiveness and safety in other conditions unless otherwise noted in the approval criteria.

II. For Commercial or HCR members with a closed formulary, a non-formulary product will only be approved if the member meets the criteria for a formulary exception in addition to the criteria outlined within this policy.

Authorization Duration

- Commercial and HCR Plans: If approved, up to a 2 month authorization may be granted.

Automatic Approval Criteria

None

References:

1. Benznidazole [package insert]. Florham Park, NJ: Exeltis USA, Inc.; December 2021.
2. Lampit [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals.; June 2023.
3. Centers for Disease Control and Prevention. Clinical Care of Chagas Disease. Available at: https://www.cdc.gov/chagas/hcp/clinical-care/index.html. Accessed August 20, 2024.