Applicable Drugs: Lampit (nifurtimox)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/2/2021

Date Last Reviewed / Revised: 5/19/2025

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - IV are met)

I. Documented diagnosis of one of the following conditions A, B or C and must meet criteria listed under applicable diagnosis:

   A. Chagas Disease – Pediatrics (American Trypanosomiasis), caused by *Trypanosoma cruzi* (must meet all):

      1. Pediatrics with age less than 18 years old.
      2. Weight ≥ 2.5 kg.
      3. Dose does not exceed:
         a. Weight 2.5 kg to <41 kg: 20 mg/kg/day.
         b. Weight ≥ 41 kg: 10 mg/kg/day (maximum 300 mg/dose).

   B. Chagas Disease – Adults (American Trypanosomiasis), caused by *Trypanosoma cruzi* (Off-Label) (must meet all):

      1. Adults ≥ 18 years old.
      2. Dose does not exceed 10 mg/kg/day (maximum 300 mg/dose).

   C. West African Trypanosomiasis, caused by *Trypanosoma brucei gambiense* (Off-Label) (must meet all):

      1. Suspected or confirmed CNS involvement (second-stage infection).
      2. Used in combination with eflornithine.
      3. Dose does not exceed 15 mg/kg/day.

II. Prescribed by or in consultation with an infectious disease specialist.

III. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

IV. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

Exclusion Criteria

- N/A

Other Criteria

- N/A

Quantity / Days Supply Restrictions

- Chagas disease (adult and pediatric):
  - 30 mg and 120 mg tablets: Up to a 30-day supply.
- West African trypanosomiasis with confirmed or suspected CNS involvement:
  - 30 and 120 mg tablets: Up to 10-day supply.

Approval Length

- **Authorization:**
  - Chagas disease – Pediatric: 60 days
  - Chagas disease – Adult: 90 days
  - West African trypanosomiasis with confirmed or suspected CNS involvement: 10 days
- **Re-Authorization:** N/A

Appendix

- N/A

References

1. Lampit® (Nifurtimox). Prescribing information. Whippany, NJ; Bayer. February 2023. Accessed May 19, 2025. https://labeling.bayerhealthcare.com/html/products/pi/Lampit_PI.pdf.
2. Bern C. Chagas disease: Antitrypanosomal drug therapy. Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed May 19, 2025. http://www.uptodate.com.
3. American Academy of Pediatrics (AAP). In: Kimberlin DW, Brady MT, Jackson MA, Long SA, eds. Red Book: 2018 Report of the Committee on Infectious Diseases. 31st ed. Itasca, IL: American Academy of Pediatrics; 2018.
4. Centers for Disease Control and Prevention. Clinical Care for Chagas Disease. Updated February 9, 2024. Accessed May 19, 2025. https://www.cdc.gov/chagas/hcp/clinical-care/index.html#cdc_clinical_care_treatment_treat_opt-treatment-options

5. WHO guidelines for the treatment of gambiense human African trypanosomiasis. Geneva: World Health Organization. Updated June 28, 2024. Accessed May 19, 2025 https://www.who.int/publications/i/item/9789240096035

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.