Generic Name: Nifurtimox

Therapeutic Class or Brand Name: Lampit®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/2/2021

Date Last Reviewed / Revised: 6/24/2024

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I - III 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.

EXCLUSION CRITERIA

- Hypersensitivity to nifurtimox or any component of the formulation; alcohol consumption during treatment.

Other Criteria

- CNS effects: May cause muscle weakness or tremors, which may impair physical abilities; patients must be cautioned about performing tasks such as operating machinery or driving if weakness or tremors occur.
- GI effects: Loss of appetite and nausea/vomiting leading to weight loss have been reported. Monitor body weight every 2 weeks during treatment and adjust dosage based on weight as needed.
- Hypersensitivity reaction: Hypersensitivity reactions, sometimes accompanied by angioedema (including laryngeal or facial edema), dyspnea, hypotension, pruritus, rash, or other severe skin reactions, have been reported. The hypersensitivity may be due to nifurtimox or an immune response caused by Chagas disease during treatment. Discontinue use at the first sign of serious hypersensitivity.
- Peripheral neuropathy: Use has been associated with peripheral neuropathy; monitor for signs and symptoms during therapy

Quantity / Days Supply Restrictions

- 30 mg and 120 mg tablets: Up to 30-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 June 24, 2024. 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 June 24, 2024. 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 2, 2024. Accessed June 24, 2024. https://www.cdc.gov/chagas/hcp/clinical-care/index.html#cdc_clinical_care_treatment_treat_opt-treatment-options
5. WHO interim guidelines for the treatment of gambiense human African trypanosomiasis. Geneva: World Health Organization. Updated August 12, 2019. Accessed June 24, 2024. https://www.who.int/publications/i/item/9789241550567