

Clinical Policy: Nifurtimox (Lampit)

Reference Number: PA.CP.PMN.256

Effective Date: 10/2020

Last Review Date: 10/2023

[Revision Log](#)

Description

Nifurtimox (Lampit[®]) is a nitrofurant antiprotozoal.

FDA Approved Indication(s)

Lampit indicated in pediatric patients (birth to less than 18 years of age and weighing at least 2.5 kg) for the treatment of Chagas disease (American trypanosomiasis), caused by *Trypanosoma cruzi* (*T. cruzi*).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that Lampit is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Chagas Disease (must meet all):

1. Diagnosis of Chagas disease confirmed by one of the following (a, b, or c) (*see Appendix D*):
 - a. Detection of circulating *T. cruzi* trypomastigotes on microscopy;
 - b. Detection of *T. cruzi* DNA by polymerase chain reaction assay;
 - c. Two positive diagnostic serologic tests showing IgG antibodies to *T. cruzi* and meeting both of the following (i and ii):
 - i. The two tests use different techniques (e.g., enzyme-linked immunosorbent assay [ELISA], immunofluorescent antibody test [IFA]);
 - ii. The two tests use different antigens (e.g., whole-parasite lysate, recombinant antigens);
2. Prescribed by or in consultation with an infectious disease specialist;
3. Member has not yet received 60 days of Lampit therapy for the current infection;
4. Dose (weight-based) does not exceed 300 mg per day (*see Appendix D for off-label dosing requests*).

Approval duration: 60 days total

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Chagas Disease (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member has not yet received 60 days of Lampit therapy for the current infection;
3. If request is for a dose increase, new dose (weight-based) does not exceed 300 mg per day (*see Appendix D for off-label dosing requests*).

Approval duration: 60 days total

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.

Approval duration: Duration of request or 60 days (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A.** Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CDC: Centers for Disease Control and Prevention

FDA: Food and Drug Administration

IgG: immunoglobulin G

T cruzi: *Trypanosoma cruzi*

WHO: World Health Organization

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s):
 - Known hypersensitivity to nifurtimox or to any of the excipients in Lampit
 - Alcohol consumption during treatment
- Boxed warning(s): none reported

Appendix D: General Information

- Diagnostic tests:
 - Laboratories offering testing for Chagas disease include ARUP Laboratories, Mayo Clinic Laboratories, and Quest Diagnostics. IgG serology is performed in the majority of cases. After obtaining initial serologic IgG test results, providers should consult their state health department and the CDC for guidance on serologic confirmation. If two results are discordant, a third assay may be needed. Donor screening tests and Immunoglobulin M (IgM) serology tests are not considered diagnostic tests.
- Off-label dosing requests for Chagas disease:

- Dosing for populations outside FDA-approved age ranges or for longer than 60 days may be appropriate and should be reviewed on a case-by-case basis. See CDC consultation resources below for questions.
- State reporting requirements:
 - According to the CDC (<https://www.cdc.gov/mmwr/volumes/67/wr/mm6726a2.htm>), in 2017 Chagas disease was reportable in six states: Arizona, Arkansas, Louisiana, Mississippi, Tennessee, and Texas.
- Consultation resources:
 - Centers for Disease Control and Prevention (CDC)
 - Parasitic Diseases: <https://www.cdc.gov/parasites/chagas/> - 404-718-4745, chagas@cdc.gov
 - CDC recommended guidance document: Bern C, Montgomery SP, Herwaldt BL, et al. Evaluation and treatment of Chagas disease in the United States: a systematic review. JAMA 2007; 298:2171.
 - CDC Drug Service: 404-639-3670
 - CDC Emergency Operations Center: 770-488-7100
 - World Health Organization (WHO)
 - Outside the US:
 - <https://www.who.int/health-topics/chagas-disease>
 -
 - American Society of Tropical Medicine and Hygiene
 - Directory of consultants: <http://www.astmh.org/education-resources/clinical-consultants-directory>

V. Dosage and Administration

Indication	Dosing Regimen					Maximum Dose
Chagas disease	Body Weight Range (kg)	Dose (mg)	Tablet # - 30 mg	Tablet # - 120 mg	Duration / Frequency PO TID for 60 days	300 mg/day
	2.5 to 4.5 kg	15 mg	½ T	—		
	4.6 to < 9 kg	30 mg	1 T	—		
	9 to < 13 kg	45 mg	1 ½ T	—		
	13 to < 18 kg	60 mg	2 T	½ T		
	18 to < 22 kg	75 mg	2 ½ T	—		
	22 to < 27 kg	90 mg	3 T	—		
	27 to < 35 kg	120 mg	4 T	1 T		
	35 to < 41 kg	180 mg	—	1 ½ T		
	41 to < 51 kg	120 mg	—	1 T		
	51 to < 71 kg	180 mg	—	1 ½ T		
	71 to < 91 kg	240 mg	—	2 T		
	≥ 91 kg	300 mg	—	2 ½ T		

VI. Product Availability

Tablets: 30 mg, 120 mg

VII. References

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Pivotal Trial

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Centers for Disease Control (CDC)

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Compendia, Guidelines, Review Articles

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Reviews, Revisions, and Approvals	Date
Policy created	10/2020
4Q 2021 annual review: no significant changes; references reviewed and updated.	10/2021
4Q 2022 annual review: no significant changes; references reviewed and updated.	10/2022
4Q 2023 annual review: updated indication from accelerated approval to traditional full approval; for Appendix D, updated previous WHO link to current link; references reviewed and updated.	10/2023