

PRIOR AUTHORIZATION POLICY

POLICY: Infectious Disease – Impavido Prior Authorization Policy

- Impavido® (miltefosine capsules – Profounda)

REVIEW DATE: 04/27/2022

OVERVIEW

Impavido, an anti-leishmanial agent, is indicated in patients ≥ 12 years of age weighing ≥ 30 kg (66 lbs) for the treatment of:

- **Visceral leishmaniasis** caused by *Leishmania donovani*.
- **Cutaneous leishmaniasis** caused by *L. braziliensis*, *L. guyanensis*, and *L. panamensis*.
- **Mucosal leishmaniasis** caused by *L. braziliensis*.¹

The treatment duration is 28 consecutive days. Limitation of use: *Leishmania* species studied in clinical trials evaluating Impavido were based on epidemiologic data; there may be geographic variation in clinical response of the same *Leishmania* species to Impavido; and the efficacy of Impavido in the treatment of other *Leishmania* species has not been evaluated.

A systematic review of four studies conducted in the Americas evaluated the efficacy of Impavido in pediatric patients ≤ 12 years of age with cutaneous leishmaniasis (n = 130).² The regimen was similar for all studies, with a target dose of 2.5 mg/kg/day (given as three times a day) for 28 days. The reported efficacy ranged from 63.1% to 82.8%.

Guidelines/Recommendations

In March 2011, Impavido was added to the World Health Organization (WHO) Essential Medicines List as an anti-leishmanial medicine.³ The current WHO recommendations for the treatment of leishmaniasis include Impavido, liposomal amphotericin B, amphotericin B deoxycholate, paromomycin (not available in the US), pentamidine, pentavalent antimonial compounds (not available in the US) with or without pentoxifylline, systemic azole therapies, and thermotherapy.^{3,4}

The Infectious Diseases Society of America (IDSA) and the American Society of Tropical Medicine and Hygiene (ASTMH) released guidelines for the management of persons with leishmaniasis in 2016.⁵ Systemic therapies, including Impavido, are recommended for the treatment of patients with cutaneous, mucosal, or visceral leishmaniasis.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Impavido. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Impavido as well as the monitoring required for adverse events and long-term efficacy, approval requires Impavido to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

04/27/2022

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RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Impavido is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Leishmaniasis.** Approve for 1 month if the patient meets the following criteria (A and B):
 - A) Patient meets one of the following (i, ii, or iii):
 - i. Patient has cutaneous leishmaniasis; OR
 - ii. Patient has mucosal leishmaniasis; OR
 - iii. Patient has visceral leishmaniasis; AND
 - B) The medication was prescribed by or in consultation with an infectious diseases specialist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Impavido is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Impavido® capsules [prescribing information]. Orlando, FL: Profounda; June 2019.
2. Uribe-Restrepo A, Cossio A, Desai MM, et al. Interventions to treat cutaneous leishmaniasis in children: a systematic review. *PLoS Negl Trop Dis*. 2018 Dec;12:e0006986.
3. Impavido, FDA Med Review. Available at: http://www.accessdata.fda.gov/drugsatfda_docs/nda/2014/204684Orig1s000MedR.pdf. Accessed on April 22, 2022.
4. World Health Organization: Control of the leishmaniases. Available at: http://apps.who.int/iris/bitstream/handle/10665/44412/WHO_TRS_949_eng.pdf;jsessionid=FAF3A6D25FA28E2D31695CEFAB9BB4AA?sequence=1. Accessed on April 15, 2022.
5. Aronson N, Herwaldt BL, Libman M, et al. Diagnosis and treatment of leishmaniasis: clinical practice guidelines by the Infectious Diseases Society of America (IDSA) and the American Society of Tropical Medicine and Hygiene (ASTMH). *Clin Inf Dis*. 2016;63(12):e202-264.