miltefeosine (Impavido®)

EOCCO POLICY

Policy Type: PA/SP Pharmacy Coverage Policy: EOCCO097

Description

Miltefosine (Impavido) is an orally administered antileishmanial medication that induces apoptosis-like cell death and stops the growth of specific *Leishmania* species.

Length of Authorization

- Initial: 28 days
- Renewal: No renewal

Quantity limits

Product Name	Dosage Form	Indication	Quantity Limit
miltefosine (Impavido)	50 mg capsules	Visceral leishmaniasis Cutaneous leishmaniasis Mucosal leishmaniasis	30 to 44 kg: 56 capsules/28 days OR ≥ 45 kg: 84 capsules/28ays

Initial Evaluation

I. Miltefosine (Impavido) may be considered medically necessary when the following criteria below are met:
   A. Member is 12 years of age or older; **AND**
   B. Member weighs at least 30 kg (66 lbs); **AND**
   C. Medication is prescribed by, or in consultation with an infectious disease specialist; **AND**
   D. A diagnosis of one of the following:
      1. Visceral leishmaniasis due to *Leishmania donovani*; **OR**
      2. Cutaneous leishmaniasis due to the following: *Leishmania braziliensis, Leishmania guyanensis,* or *Leishmania panamensis*; **OR**
      3. Mucosal leishmaniasis due to *Leishmania braziliensis*; **AND**
   E. Laboratory confirmation of leshmaniasis species were identified following **ONE** of the recommended tests provided by the Centers for Disease Control and Prevention (CDC) listed here:
      1. Stained slides (using tissue from biopsy specimens, impression smears or dermal scrapings)
      2. Culture medium
      3. Polymerase chain reaction (PCR)
      4. Serologic testing (e.g., rK39 Rapid Test); **AND**

F. For the diagnosis of visceral leishmaniasis, treatment with liposomal amphotericin B (Ambisome) has been ineffective, contraindicated, or not tolerated.

II. Miltefosine (Impavido) is considered not medically necessary when criteria above are not met and/or when used for:
   A. The treatment of leishmaniasis outside of the visceral/cutaneous/mucosal settings, and not due to the species associated with visceral/cutaneous/mucosal leishmaniasis.

Supporting Evidence

I. Miltefosine (Impavido) is FDA-approved in the adolescents and adults ≥ 12 years and older weighing ≥ 30 kg (66lbs).
II. For the treatment of visceral leishmaniasis, the safety and efficacy was studied in one randomized, open-label, active-controlled (amphotericin B) trial in Bihar, India. The final cure rates for miltefosine (Impavido) and amphotericin B were 94% and 97%, respectively. Final cure was defined as initial cure at end of therapy plus absence of signs and symptoms of visceral leishmaniasis at six months follow up.
III. For the treatment of cutaneous leishmaniasis, the safety and efficacy was studied in a placebo controlled study in Colombia, Guatemala and Brazil. The finally cure rates at 95% CI with P-value <0.0001 were reported:
   A. Colombia: 82% miltefosine (Impavido) vs 30% placebo
   B. Guatemala: 48% miltefosine (Impavido) vs 20% placebo
   C. Brazil: 76.3% miltefosine (Impavido), placebo was not reported.
IV. For the treatment of mucosal leishmaniasis, the safety and efficacy was studied in a single-arm study in Bolivia that included 79 patients. At the end of therapy, reported at 12 months, 49 patients (62%) had complete resolution of edema, erythema, infiltration, and erosion from the involved mucosal sites.
V. The CDC has specific guidelines for leshmaniasis confirmation test. They can be found here: https://www.cdc.gov/parasites/leishmaniasis/resources/pdf/cdc_diagnosis_guide_leishmaniasis_2016.pdf.

Investigational or Not Medically Necessary Uses

I. The treatment of leishmaniasis outside of the visceral/cutaneous/mucosal settings, and not due to the species associated with visceral/cutaneous/mucosal leishmaniasis.
   A. There is limited evidence to suggest the safety and efficacy of miltefosine (Impavido) outside of the FDA approved leshmaniasis settings and the specific species accordingly.

References

1. Impavido [Prescribing Information]. Wilmington, DE: Paladin Therapeutics, Inc. March 2014.
2. Centers for Disease Control and Prevention. Diagnosis and Treatment of Leishmaniasis: Clinical Practice Guidelines by the Infectious Disease Society (IDSA) and the American Society of Tropical Medicine and Hygiene (ASTMH). October 2018. Available at: https://www.cdc.gov/parasites/leishmaniasis/health_professionals/index.html#dx

Policy Implementation/Update:

Date Created	April 2016
Date Effective	August 2016
Last Updated	October 2019
Last Reviewed	4/2016, 10/2019

Action and Summary of Changes	Date
Transitioned criteria into policy with the following additions: supporting evidence, investigational section and CDC diagnostic recommendations.	10/2019