



Commercial/Healthcare Exchange PA Criteria

Effective: April 27, 2020

Prior Authorization: Impavido (miltefosine)

Products Affected: Impavido (miltefosine) oral capsule

Medication Description:

Miltefosine is an anti-leishmanial agent, but its specific mode of action against Leishmania species is unknown. It is the only agent FDA-approved for use in the United States for cutaneous leishmaniasis, and is a viable option for the treatment of cutaneous, visceral, and mucosal leishmaniasis due to various species of Leishmania. Miltefosine is indicated for the treatment of visceral leishmaniasis due to *Leishmania donovani*, cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*, and mucosal leishmaniasis due to *Leishmania braziliensis*. While unknown for certain, the likely mechanism of action involves interaction with lipids (phospholipids and sterols), including membrane lipids, inhibition of cytochrome c oxidase (mitochondrial function), and apoptosis-like cell death.

Covered Uses:

Miltefosine is indicated for the treatment of visceral leishmaniasis due to *Leishmania donovani*, cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, and *Leishmania panamensis*, mucosal leishmaniasis due to *Leishmania braziliensis*.

Exclusion Criteria:

Miltefosine has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions:

1. If the individual is pregnant
2. Patients who have Sjögren-Larsson-Syndrome
3. Patients who have a hypersensitivity to miltefosine or any of its excipients

Required Medical Information:

Diagnosis: Leishmaniasis- treatment of visceral (caused by *Leishmania donovani*), cutaneous (caused by *L. braziliensis*, *L. guyanensis*, and *L. panamensis*), and mucosal leishmaniasis (caused by *L. braziliensis*)

Age Restrictions: 12 years of age or older

Prescriber Restrictions: N/A

Coverage Duration: 28 days

Other Criteria:

Approve Impavido if the patient meets the following criteria:

- A. The patient has a documented diagnosis of visceral leishmaniasis due to *Leishmania donovani*, OR cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, or *Leishmania panamensis*, OR mucosal leishmaniasis due to *Leishmania braziliensis*
 - a. Weight based dosing
 - i. If patient weighs 30 to 44 kg: 56 capsules/28 days

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Confidential Information

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- ii. If patient weighs ≥ 45 kg: 84 capsules/28 days

References:

1. Impavido (miltefosine) package insert. Wilmington, DE: Paladin Therapeutics; 2014.
2. Impavido. Lexicomp Online [Internet database], Hudson, Ohio: Wolters Kluwer Health, Inc; July 01, 2016.
3. Micromedex® 2.0, (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. Available at: <http://www.micromedexsolutions.com/> [Accessed on July 1, 2016].

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	7/02/2016
2	Update	CCI adoption of EH policy Removal for CCI pa to indication policy	Reviewed indications and exclusions to FDA label	4/27/2020