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

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