UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Impavido

Program	Prior Authorization
Medication	Impavido (miltefosine)
Issue Date	6/2016
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

Impavido (miltefosine) is an antileishmanial agent indicated in adults and adolescents ≥12 years of age and weighing ≥30 kg (66 lbs) for 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*. The efficacy of Impavido in the treatment of other *Leishmania* species has not been evaluated. Impavido should be administered as a dose of one 50 mg capsule two to three times daily for 28 consecutive days.

2. Coverage Criteria:

A. Authorization

1. **Impavido** will be approved based on the following criterion:

   a. Diagnosis of **one** of the following:

      (1) Visceral leishmaniasis due to *Leishmania donovani*
      (2) Cutaneous leishmaniasis due to *Leishmania braziliensis*, *Leishmania guyanensis*, or *Leishmania panamensis*
      (3) Mucosal leishmaniasis due to *Leishmania braziliensis*.
      (4) Primary Amebic Meningoencephalitis (PAM) [Off Label]

Authorization will be issued for 28 days.

3. References:

1. Impavido (prescribing information). Paladin Therapeutics Inc. Wilmington, DE. March 2014.
2. CDC Guidelines. *Naegleria fowleri* – Primary Amebic Meningoencephalitis (PAM) – Amebic Encephalitis. http://www.cdc.gov/parasites/naegleria/index.html. February 2017.

Program	Prior Authorization - Impavido (miltefosine)
Change Control	
Date	Change
6/2016	New program
10/2016	Added criteria for coverage of Amebic Meningoencephalitis and updated references
10/2017	Annual Review. Updated references.
3/2018	Clarified authorization duration should be 28 days