UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1191-9
Program	Prior Authorization/Notification
Medication	Impavido (miltefosine)
P&T Approval Date	6/2016, 10/2016, 10/2017, 4/2018, 3/2019, 3/2020, 3/2021, 3/2022, 3/2023
Effective Date	6/1/2023; Oxford only: 6/1/2023

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]:

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)
      (5) Keratitis due to *Acanthamoeba*
      (6) Amebic encephalitis due to *Balamuthia mandrillaris*

Authorization will be issued for 28 days

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Supply limits may be in place
- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

4. References:

1. Impavido [prescribing information]. Orlando FL: Profounda, Inc.: May 2021
2. CDC Guidelines. *Naegleria fowleri* – Primary Amebic Meningoencephalitis (PAM) – Amebic Encephalitis. http://www.cdc.gov/parasites/naegleria/index.html. Accessed January 2023.
3. CDC Guidelines. Parasites – *Acanthamoeba* - Granulomatous Amebic Encephalitis (GAE); Keratitis. https://www.cdc.gov/parasites/acanthamoeba/index.html. Accessed January 2023.
4. CDC Guidelines. *Balamuthia mandrillaris* - Granulomatous Amebic Encephalitis (GAE). https://www.cdc.gov/parasites/balamuthia/index.html. Accessed January 2023.

Program	Prior Authorization/Notification - Impavido
Change Control	
Date	Change
6/2016	New program
10/2016	Added criteria for coverage of Amebic Meningoencephalitis
10/2017	Annual Review. Updated references.
4/2018	Authorization timeframe updated.
3/2019	Annual Review. Added *Acanthamoeba* keratitis, added statement regarding use of automated process and updated references.
3/2020	Annual review. Added encephalitis due to *Balamuthia mandrillaris.* Updated references.
3/2021	Annual review. No changes.
3/2022	Annual review. Removed reference to off label indications. Updated references.
3/2023	Annual review. Added mandate language.