

Impavido (miltefosine)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 month

Medications	Quantity Limit
Impavido (miltefosine)	84 capsules per fill; 1 fill per 30 days

APPROVAL CRITERIA

Requests for Impavido (miltefosine) may be approved if the following criteria are met:

- I. Individual is 12 years of age or older (and weighing at least 30 kg);
AND
- II. Individual is using for the treatment of cutaneous, mucosal, or visceral leishmaniasis;

OR

- III. Individual is using for the treatment of free-living ameba infections [examples include but not limited to primary amebic meningoencephalitis caused by *Naegleria fowleri* and granulomatous amebic encephalitis or other infections caused by *Balamuthia mandrillaris* or *Acanthamoeba* (AHFS)];

OR

- IV. Individual started treatment in the hospital and requires continued outpatient therapy for an organism susceptible to Impavido (miltefosine).

Impavido (miltefosine) may not be approved for the following:

- I. Individual has a history of Sjögren-Larsson-Syndrome.

Note: Impavido (miltefosine) has a black box warning for embryo-fetal toxicity. Impavido should not be administered to pregnant women and a serum or urine pregnancy test should be performed in females of reproductive potential prior to prescribing. Females of reproductive age should be advised to use effective contraception during and for 5 months following Impavido therapy.

Key References:

1. Aronson N, Herwaldt BL, Libman M, et. al. Diagnosis and Treatment of Leishmaniasis: Clinical Practice Guidelines by the Infectious Diseases Society of America (IDSA) and the American Society of Tropical Medicine and Hygiene (ASTMH). Clin Infect Dis. 2016;63(12):e202-e264.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: December 10, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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