

Market Applicability															
Market	DC	FL & FHK	FL MMA	FL LTC	GA	KS	KY	LA	MD	NJ	NV	NY	TN	TX	WA
Applicable	X	X	NA	NA	X	NA	X	X	X	X	X	X	NA	NA	X

*FHK- Florida Healthy Kids

Impavido (miltefosine)

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

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* (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. Miltefosine 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 miltefosine therapy.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.

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State Specific Mandates		
State name	Date effective	Mandate details (including specific bill if applicable)
N/A	N/A	N/A

Key References:

Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2018.
 URL: <http://www.clinicalpharmacology.com>. Updated periodically.

DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed January 5, 2018.

DrugPoints® System (electronic version). Truven Health Analytics, Greenwood Village, CO. Updated periodically.

Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2018; Updated periodically.

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