Drug Coverage Policy

Effective Date……08/15/2024
Coverage Policy Number…… IP0210
Policy Title…… Impavido

Infectious Disease – Impavido

- Impavido® (miltefosine capsules – Profounda)

INSTRUCTIONS FOR USE
The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment and have discretion in making individual coverage determinations. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

Cigna Healthcare Coverage Policy

OVERVIEW
Impavido, an anti-leishmanial agent, is indicated in patients ≥ 12 years of age weighing ≥ 30 kg (66 lbs) for the treatment of:[1]

- **Visceral leishmaniasis** caused by *Leishmania donovani*.
- **Cutaneous leishmaniasis** caused by *L. braziliensis*, *L. guyanensis*, and *L. panamensis*.
- **Mucosal leishmaniasis** caused by *L. braziliensis*.

The treatment duration is 28 consecutive days. Limitation of use: *Leishmania* species studied in clinical trials evaluating Impavido were based on epidemiologic data; there may be geographic variation in clinical response of the same *Leishmania* species to Impavido; and the efficacy of Impavido in the treatment of other *Leishmania* species has not been evaluated.

A systematic review of four studies conducted in the Americas evaluated the efficacy of Impavido in pediatric patients ≤ 12 years of age with cutaneous leishmaniasis (n = 130).[2] The regimen was similar for all studies, with a target dose of 2.5 mg/kg/day (given as three times a day) for 28 days. The reported efficacy ranged from 63.1% to 82.8%.

Medical Necessity Criteria

Impavido is considered medically necessary when the following criteria are met:

FDA-Approved Indication

1. **Leishmaniasis.** Approve for 1 month if the patient meets BOTH of the following (A and B):
   - **A)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** Patient has cutaneous leishmaniasis; OR
     - **ii.** Patient has mucosal leishmaniasis; OR
     - **iii.** Patient has visceral leishmaniasis; AND
   - **B)** The medication is prescribed by or in consultation with an infectious diseases specialist.

Other Uses with Supportive Evidence

2. **Ameba Related Infections**. Approve for 1 month if the patient meets BOTH of the following (A and B):
   - **A)** Treatment of infection due to *Acanthamoeba*, *Balamuthia mandrillaris*, or *Naegleria fowleri* [for example, keratitis, granulomatous amebic encephalitis, primary amebic meningoencephalitis (PAM)]; AND
   - **B)** The medication is prescribed by or in consultation with an infectious diseases specialist.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Receipt of sample product does not satisfy any criteria requirements for coverage.

Conditions Not Covered

Any other use is considered experimental, investigational, or unproven (criteria will be updated as new published data are available).

References

1. Impavido® capsules [prescribing information]. Orlando, FL: Profounda; August 2023.
2. Uribe-Restrepo A, Cossio A, Desai MM, et al. Interventions to treat cutaneous leishmaniasis in children: a systematic review. *PLoS Negl Trop Dis*. 2018 Dec;12:e0006986.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Revision	**Policy Name Change: Updated** Policy Name from "Miltefosine" to "Infectious Disease – Impavido."	08/15/2024

	Leishmaniasis: Removed the criteria specifying treatment for infections caused by specific Leishmania species. **Added** the requirement for medication to be prescribed by or in consultation with an infectious disease specialist. **Ameba Related Infections: Added** the requirement for medication to be prescribed by or in consultation with an infectious disease specialist.	

The policy effective date is in force until updated or retired.

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