

[Date]

[Medical Director]
[Insurance Company Name]
[Address] [City, State ZIP]

Patient Name:
Patient Date of Birth:
Policy Number:
Claim Number:

RE: Approval to Use Impavido (Miltefosine) As Medically Necessary

Dear [Medical Director]:

I am writing on behalf of my patient, [patient name], who has been diagnosed with [visceral, cutaneous, mucosal] leishmaniasis. It is medically necessary to use Impavido (Miltefosine) in [his/her] treatment. Impavido is the only FDA-approved therapy for all three forms of leishmaniasis. It is available in oral dosage form and requires only one 28-day treatment cycle.

This letter provides information about [patient name]'s medical history, diagnosis and proposed treatment with Impavido. Further, I have attached [patient name]'s medical records, a dossier on use of Impavido in treating leishmaniasis, and the product's package insert. On behalf of [patient name], I request approval for the use of medically necessary Impavido.

Leishmaniasis is a parasitic disease generally found in parts of the tropics, subtropics, and southern Europe. Leishmaniasis is caused by infection with *Leishmania* parasites, which are spread by the bite of phlebotomine sand flies. There are several different forms of leishmaniasis in people. The most common forms are cutaneous leishmaniasis, which causes skin sores, and visceral leishmaniasis, which affects several internal organs (usually spleen, liver, and bone marrow). Overall, leishmaniasis is found in parts of more than 90 countries.

Cases of leishmaniasis evaluated in the United States typically reflect travel and immigration patterns. For example, many of the cases of cutaneous leishmaniasis in U.S. civilian travelers have been acquired in common tourist destinations in Latin America, such as in Costa Rica. U.S. military personnel have become infected in various countries, such as Iraq and Afghanistan. However, occasional cases of cutaneous leishmaniasis have been acquired in Texas and Oklahoma. No cases of visceral leishmaniasis are known to have been acquired in the United States. In 1-10% of patients with New World CL, *Leishmania* disseminates from the skin to the nasooropharyngeal mucosa, resulting in mucosal leishmaniasis and destruction of nasal and pharyngeal structures. Death may occur due to complicating aspiration pneumonia.

[This is where the physician should provide a brief summary of patient history, including:

- Description of patient's condition and the basis for diagnosis
- Circumstances surrounding care

- Previous diagnostic tests, therapies, and any complications
- Any other relevant information]

Please approve using Impavido on [patient name]'s behalf as recommended. If I can provide any additional information, please contact me at [insert practice phone number]. Thank you in advance for your immediate attention to this request.

Regards,

[Provider]

Encl.

Clinical patient notes and lab reports
Dossier on use of Impavido in treating leishmaniasis
FDA-approved Prescribing Information