[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 Acanthamoeba Keratitis. Acanthamoeba keratitis is a serious, rare, and painful eye condition which affects the cornea of the eye, the transparent part of the eye through which the light enters. The condition is caused by a single celled amoeba, called Acanthamoeba. Prolonged infection can result in loss of vision. It is medically necessary to use Impavido (Miltefosine) in [his/her] treatment. Impavido has received FDA-orphan drug designation for Acanthamoeba Keratitis and is approved for all three forms of Leishmaniasis. It is available in oral dosage form and requires only one to two 28-day treatment cycles. Prior to Impavido’s approval, The CDC had an expanded access investigational new drug (IND) protocol in effect with the Food and Drug Administration to make miltefosine available directly from CDC for treatment of FLA in the United States. The expanded access IND use of miltefosine for treatment of FLA is partly supported by 26 case reports of FLA infection in which miltefosine was part of the treatment regimen (Division of Foodborne, Waterborne, and Environmental Diseases, National Center for Emerging and Zoonotic Infectious Diseases, CDC, unpublished data, 2013). Miltefosine generally is well-tolerated, with gastrointestinal symptoms the most commonly reported adverse effects.

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, Acanthamoeba Keratitis and other amoebic infections, and the product’s package insert. On behalf of [patient name], I request approval for the use of medically necessary Impavido.

Acanthamoeba keratitis (AK), a painful corneal infection that may lead to vision loss or enucleation, is caused by the ubiquitous free-living Acanthamoeba spp. (1–4). AK occurs primarily among users of soft contact lenses (5), with an estimated US annual incidence of 1–2 cases per million contact lens users (6). Acanthamoeba keratitis is a rare but serious infection of the eye that can result in permanent visual impairment or blindness. This infection is caused by a microscopic, free-living ameba (single-celled living organism) called Acanthamoeba. Acanthamoeba causes Acanthamoeba keratitis when it infects the transparent outer covering of the eye called the cornea. Acanthamoeba amebas are very common in nature and can be found in bodies of water (for example, lakes and oceans), soil, and air.

The symptoms of Acanthamoeba keratitis can be very similar to the symptoms of other eye infections. These symptoms, which can last for several weeks or months, may include:

* Eye pain
* Eye redness
* Blurred vision
* Sensitivity to light
* Sensation of something in the eye
* Excessive tearing

Early diagnosis is essential for effective treatment of Acanthamoeba keratitis. Several prescription eye medications are available for treatment. However, the infection can be difficult to treat.

[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/Acanthamoeba

FDA-approved Prescribing Information

References

1. Awwad ST, Petroll WM, McCulley JP, Cavanagh HD. Updates in Acanthamoeba keratitis. Eye Contact Lens. 2007;33:1–8. DOI: 10.1097/ICL.0b013e31802b64c1

2. Hammersmith KM. Diagnosis and management of Acanthamoeba keratitis. Curr Opin Ophthalmol. 2006;17:327–31. DOI: 10.1097/01. icu.0000233949.56229.7d

3. Naginton J, Watson PG, Playfair TJ, McGill J, Jones BR, Steele AD. Amoebic infection of the eye. Lancet. 1974;2:1537–40. DOI: 10.1016/S0140-6736(74)90285-2

4. Visvesvara GS, Jones DB, Robinson NM. Isolation, identification, and biological characterization of Acanthamoeba polyphaga from a human eye. Am J Trop Med Hyg. 1975;24:784–90.