Micafungin (Mycamine®)	**Place of Service** **Hospital Administration** **Home Infusion Administration** **Infusion Center Administration** **Office Administration** **Outpatient Facility Administration*** [***Prior authorization required – see section (1)] **HCPCS** • **J2247** per 1 mg (micafungin sodium (par pharm) not therapeutically equivalent to j2248) • **J2248** per 1 mg (Micafungin sodium injection)

Conditions listed in policy (*see criteria for details*)

- Antifungal prophylaxis in cancer patients
- Candida osteomyelitis or candida septic arthritis
- Chronic disseminated candidiasis (hepatosplenic candidiasis)
- Esophageal candidiasis
- Intra-abdominal candidiasis
- Invasive aspergillosis
- Invasive candidiasis/candidemia
- Oropharyngeal candidiasis
- Pulmonary aspergillosis

AHFS therapeutic class: Antifungal agent; echinocandin..

Mechanism of action: Semisynthetic, echinocandin antifungal agent.

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

**** CRITERIA FOR HOSPITAL OUTPATIENT FACILITY ADMINISTRATION****

AAAAI Guidelines 2011, MCG™ Care Guidelines, 19th edition, 2015

Members with the following plans: **PPO, Direct Contract HMO, and when applicable: ASO/Shared Advantage/HMO (non-direct contract)**, may be required to have their medication administered at a preferred site of service, including the home, a physician's office, or an independent infusion center not associated with a hospital.

For members that cannot receive infusions in the preferred home or ambulatory setting AND meet one of the following criteria points, drug administration may be performed at a hospital outpatient facility infusion center.

ADMINISTRATION OF MYCAMINE INFUSIONS IN THE HOSPITAL OUTPATIENT FACILITY SITE OF CARE REQUIRES ONE OF THE FOLLOWING: (*Supporting Documentation must be submitted to support the need for additional clinical monitoring)* 1. Patient is receiving their first infusion of Mycamine or is being re-initiated on Mycamine after at least 6 months off therapy. *Subsequent doses will require medical necessity for continued use in the hospital outpatient facility site of care.* Or Additional clinical monitoring is required during administration as evidenced by one of the following: 2. Patient experienced a previous hypersensitivity event with Mycamine infusions based on documentation submitted. 3. Patient is currently experiencing hypersensitivity events with Mycamine infusions based on documentation submitted. 4. Patient is clinically unstable based on documentation submitted. 5. Patient is clinically, physically, or cognitively unstable based on documentation submitted	

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Mycamine® (micafungin) for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Antifungal prophylaxis in cancer patients

1. Being used as antifungal prophylaxis for cancer patients at high risk of febrile neutropenia [e.g. du regimen, AML/MDS patient, undergoing HCST], **AND**
2. Inadequate response, intolerance, or contraindication to fluconazole, voriconazole or posaconazole

Covered Doses
18 years and older: Up to 150 IV mg daily
4 months of age to less than 18 years of age: Up to 1 mg/kg IV daily (up to a maximum of 50 mg daily)

Coverage Period
Up to 2 months of therapy and reassess continued efficacy

ICD-10:
H44.001, H44.002, H44.003, H44.009

Candida osteomyelitis or candida septic arthritis

1. Diagnosis only

Covered Doses
Up to 100 mg IV daily

Coverage Period
2 weeks

ICD-10:
B37.89

Chronic disseminated candidiasis (hepatosplenic candidiasis)

1. Diagnosis only

Covered Doses
Up to 100 mg IV daily

Coverage Period
2 months of therapy and reassess for continued efficacy

ICD-10:
B37.7

Esophageal candidiasis

1. Inadequate response, intolerance, or contraindication to fluconazole, OR proven culture resistant to fluconazole

Covered Doses

18 years and older: Up to 150 mg daily by intravenous infusion
4 months of age to less than 18 years of age:

- 30 kg or less: Up to 3 mg/kg daily by intravenous infusion
- >30 kg: Up to 2.5 mg/kg daily by intravenous infusion (up to a maximum of 150 mg daily)

Coverage Period
Up to 2 months of therapy and reassess continued efficacy

ICD-10:
B37.81

Intra-abdominal candidiasis

1. Diagnosis only (includes peritonitis)

Covered Doses
18 years and older: Up to 100 mg IV daily
4 months of age to less than 18 years of age: Up to 2 mg/kg IV daily (up to a maximum of 100 mg daily)
Less than 4 months of age: 4 mg/kg IV daily

Coverage Period
Up to 2 months of therapy and reassess continued efficacy

ICD-10:
B37.9

Invasive aspergillosis

1. Inadequate response, intolerance, or contraindication to an azole antifungal (i.e., itraconazole, voriconazole, posaconazole), or proven culture resistant to an azole antifungal

Covered Doses
Up to 150 mg IV daily

Coverage Period
Up to 2 months of therapy and reassess continued efficacy

ICD-10:
B44.0-B44.2, B44.7,B44.89, B44.9, B48.4

Oropharyngeal candidiasis

1. Inadequate response, intolerance, or contraindication to an azole antifungal (ie: fluconazole, itraconazole, voriconazole, and posaconazole), OR proven culture resistant to an azole antifungal

Covered Doses
Up to 150 mg IV daily

Coverage Period
Up to 2 months of therapy and reassess continued efficacy

ICD-10:
B37.0, B37.83

Pulmonary aspergillosis

1. Inadequate response, intolerance, or contraindication to itraconazole or voriconazole

Covered Doses
Up to 150 mg IV daily

Coverage Period
Up to 2 months of therapy and reassess continued efficacy

ICD-10:
B44.0-B44.2, B44.7,B44.89, B44.9, B48.4

(3) The following condition(s) DO NOT require Prior Authorization/Preservice
All requests for Mycamine® (micafungin) for conditions NOT LISTED in section 3 must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Invasive Candidiasis/Candidemia

Covered Doses
18 years and older: Up to 150 mg IV daily
4 months of age to less than 18 years of age: Up to 2 mg/kg IV daily (up to a maximum of 100 mg daily)
Less than 4 months of age: Up to 4 mg/kg IV daily

Coverage Period
Up to 2 months of therapy and reassess continued efficacy

ICD-10:
B37.7

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How supplied:
50 mg, 100 mg (Intravenous powder for solution)

(6) References

- AHFS®. Available by subscription at http://www.lexi.com
- DrugDex®. Available by subscription at http://www.thomsonhc.com
- Guidelines for the Prevention and Treatment of Opportunistic Infections in Adults and Adolescents with HIV. Available at: https://clinicalinfo.hiv.gov/sites/default/files/guidelines/documents/Adult_OI.pdf
- Mycamine® (micafungin) [Prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; 7/2020.
- National Comprehensive Cancer Network. Prevention and treatment of cancer-related infections (Volume 2.2020). Available at: www.nccn.org/
- Pappas PG, Kauffman CA, Andes DR, et al. Clinical practice guideline for the management of Candidiasis: 2016 update by the Infectious Disease Society of America. Clin Infect Dis 2016; 62(4):e1-e50.
- Patterson TF, Thompson GR, Denning DW, et al: Practice guidelines for the diagnosis and management of aspergillosis: 2016 update by the Infectious Diseases Society of America. Clin Infect Dis 2016; 63(4):e1-e60.
- Taplitz RA, Kennedy EB, Bow EJ et al. Antimicrobial prophylaxis for adult patients with cancer-related immunosuppression: ASCO and IDSA clinical practice guideline update. J Clin Oncol 2018;36:3043-3054.

(7) Policy Update

Date of last revision: 3Q2022
Date of next review: 2Q2023
Changes from previous policy version:
- No clinical change to policy following revision.

BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee