Original Effective Date: 07/01/2016
Current Effective Date: 03/07/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
Policy Number: C9347-A

Mycamine (micafungin)

PRODUCTS AFFECTED

Mycamine (micafungin), micafungin

COVERAGE POLICY

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Coverage Guideline must be read in its entirety to determine coverage eligibility, if any. This Coverage Guideline provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide Molina Healthcare complete medical rationale when requesting any exceptions to these guidelines.

Documentation Requirements:
Molina Healthcare reserves the right to require that additional documentation be made available as part of its coverage determination; quality improvement; and fraud; waste and abuse prevention processes. Documentation required may include, but is not limited to, patient records, test results and credentials of the provider ordering or performing a drug or service. Molina Healthcare may deny reimbursement or take additional appropriate action if the documentation provided does not support the initial determination that the drugs or services were medically necessary, not investigational or experimental, and otherwise within the scope of benefits afforded to the member, and/or the documentation demonstrates a pattern of billing or other practice that is inappropriate or excessive.

DIAGNOSIS:
Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses, Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses without meningoencephalitis and/or ocular dissemination, Treatment of Esophageal Candidiasis, Prophylaxis of Candida Infections in patients undergoing Hematopoietic Stem Cell Transplantation (HSCT), Invasive aspergillosis salvage therapy, candidiasis osteoarticular infection (osteomyelitis or septic arthritis)-alternative therapy, chronic disseminated candidiasis, refractory oropharyngeal candidiasis, empiric antifungal therapy in neutropenic fever, cardiovascular system infections, intraabdominal infections

REQUIRED MEDICAL INFORMATION:
This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. If a drug within this policy receives an updated FDA label within the last 180 days, medical necessity for the member will be reviewed using the updated FDA label information along with state and federal requirements, benefit being administered and formulary preferencing. Coverage will be determined on a case-by case basis until the criteria can be updated through Molina Healthcare, Inc. clinical governance. Additional information may be required on a case-by-case basis to allow for adequate review. When the requested drug product for coverage is dosed by weight, body surface area or other member specific measurement, this data element is required as part of the medical necessity review. The Pharmacy and Therapeutics Committee has determined that the drug benefit shall be a

mandatory generic and that generic drugs will be dispensed whenever available.

A. FOR ALL INDICATIONS:

1. Documentation member has an infection caused by or strongly suspected to be caused by a type of pathogen and site of infection within the FDA label or compendia supported.
   AND
2. Documentation of inadequate treatment response, serious side effects, contraindication, or non-susceptibility to an antifungal treatment- PREFERRED oral Fluconazole, IV voriconazole, IV amphotericin (if diagnostically appropriate)

CONTINUATION OF THERAPY:

A. FOR ALL INDICATIONS:

1. Adherence to therapy at least 85% of the time as verified by the prescriber or member's medication fill history OR adherence less than 85% of the time due to the need for surgery causing temporary discontinuation
   AND
2. Prescriber attests to or clinical reviewer has found no evidence of intolerable adverse effects or drug toxicity
   AND
3. Documentation that the request for continuation of treatment aligns with a duration of therapy that is supported by FDA label, treatment guidelines, or compendia supported OR Documentation that continuation of therapy is recommended and rationale for continued medical necessity is provided [DOCUMENTATION REQUIRED]

DURATION OF APPROVAL:

Initial authorization: for up to 6 months as clinically appropriate based on indication, Continuation of Therapy: for up to 6 months as clinically appropriate based on indication

PRESCRIBER REQUIREMENTS:

Prescribed by or in consultation with an infectious disease specialist. [If prescribed in consultation, consultation notes must be submitted with initial request and reauthorization requests]

AGE RESTRICTIONS:

None

QUANTITY:

Dosage, frequency, and total treatment duration must be supported by FDA label or compendia supported dosing for prescribed indication

PLACE OF ADMINISTRATION:

The recommendation is that infused medications in this policy will be for pharmacy or medical benefit coverage administered in a place of service that is a non-inpatient hospital facility-based location.

DRUG INFORMATION

ROUTE OF ADMINISTRATION:

Intravenous

DRUG CLASS:

Antifungal - Glucan Synthesis Inhibitors (Echinocandins)

FDA-APPROVED USES:

MYCAMINE® is indicated in adult and pediatric patients for:

- Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis

and Abscesses in adult and pediatric patients 4 months of age and older.
- Treatment of Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses without meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age.
- Treatment of Esophageal Candidiasis in adult and pediatric patients 4 months of age and older.
- Prophylaxis of Candida Infections in adult and pediatric patients 4 months of age and older undergoing Hematopoietic Stem Cell Transplantation (HSCT).

Limitations of Use: The safety and effectiveness of Mycamine have not been established for the treatment of candidemia with meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age as a higher dose may be needed.
Mycamine has not been adequately studied in patients with endocarditis, osteomyelitis or meningoencephalitis due to Candida. The efficacy of Mycamine against infections caused by fungi other than Candida has not been established.

COMPENDIAL APPROVED OFF-LABELED USES:
Invasive aspergillosis salvage therapy, candidiasis osteoarticular infection (osteomyelitis or septic arthritis)-alternative therapy, chronic disseminated candidiasis, refractory oropharyngeal candidiasis, empiric antifungal therapy in neutropenic fever, cardiovascular system infections, intraabdominal infections (i.e., peritonitis, abscess)

APPENDIX

APPENDIX:
None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:
None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
All other uses of Mycamine (micafungin) are considered experimental/investigational and therefore, will follow Molina's Off- Label policy. Mycamine is contraindicated in persons with known hypersensitivity to micafungin, any component of Mycamine, or other echinocandins.

OTHER SPECIAL CONSIDERATIONS:
None

CODING/BILLING INFORMATION

Note: 1) This list of codes may not be all-inclusive. 2) Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement

HCPCS CODE	DESCRIPTION
J2248	Injection, micafungin sodium 1 mg
J2247	Injection, micafungin sodium (par pharm) not therapeutically equivalent to J2248, 1 mg

AVAILABLE DOSAGE FORMS:
Micafungin Sodium SOLR 50MG single-dose vial
Mycamine SOLR 50MG single-dose vial
Micafungin Sodium SOLR 100MG single-dose vial
Mycamine SOLR 100MG single-dose vial

REFERENCES

1. Mycamine (micafungin) [prescribing information]. Northbrook, IL: Astellas Pharma US Inc; July 2020.
2. Freifeld AG, Bow EJ, Sepkowitz KA, et al; Infectious Diseases Society of America. Clinical practice guideline for the use of antimicrobial agents in neutropenic patients with cancer: 2010 update by the Infectious Diseases Society of America. Clin Infect Dis. 2011;52(4):e56-e93
3. Patterson TF, Thompson GR 3rd, 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. doi:10.1093/cid/ciw326. http://cid.oxfordjournals.org/content/early/2016/06/22/cid.ciw326.full.pdf+html
4. Stevens DL, Bisno AL, Chambers HF, et al. Practice guidelines for the diagnosis and management of skin and soft tissue infections: 2014 update by the infectious diseases society of America [published online June 18, 2014]. Clin Infect Dis. 2014;59(2):e10-52. doi: 10.1093/cid/ciu296.
5. Pappas, P. G., Kauffman, C. A., Andes, D. R., Clancy, C. J., Marr, K. A., Ostrosky-Zeichner, L., Sobel, J. D. (2015). Clinical practice guideline for the management of candidiasis: 2016 update by the Infectious Diseases Society of America. Clinical Infectious Diseases, 62(4). doi:10.1093/cid/civ933

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Drug Class References	Q1 2024
REVISION- Notable revisions: Products Affected Diagnosis Required Medical Information Continuation of Therapy Duration of Approval FDA-Approved Uses Compendial Approved Off-Labeled Uses HCPCS Code and Description Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file