Mycamine (micafungin)
Policy Number: C9347-A

CRITERIA EFFECTIVE DATES:

ORIGINAL EFFECTIVE DATE	LAST REVIEWED DATE	NEXT REVIEW DATE
07/2016	06/2018	06/2019
J CODE	**TYPE OF CRITERIA**	**LAST P&T APPROVAL**
J2248	RxPA	Q3

PRODUCTS AFFECTED:
Mycamine (micafungin)

DRUG CLASS:
intravenous echinocandin antifungal agent

ROUTE OF ADMINISTRATION:
Intravenous

PLACE OF SERVICE:
Buy and Bill

AVAILABLE DOSAGE FORMS:
50 and 100mg powder for injection

FDA-APPROVED USES:
Treatment of Patients with Candidemia, Acute Disseminated Candidiasis, Candida Peritonitis and Abscesses, Treatment of Patients with Esophageal Candidiasis, Prophylaxis of Candida Infections in Patients Undergoing Hematopoietic Stem Cell Transplantation
NOTE: The efficacy of MYCAMINE against infections caused by fungi other than Candida has not been established.

COMPENDIAL APPROVED OFF-LABELED USES:

COVERAGE CRITERIA: INITIAL AUTHORIZATION

DIAGNOSIS: For the treatment of candidemia and invasive candidiasis
REQUIRED MEDICAL INFORMATION:

1. Failure of a consistent trial of formulary medications (fluconazole), (for treatment of Candidemia, acute disseminated candidiasis, Candida peritonitis, abscesses, or esophageal candidiasis)
   OR
2. Documented allergy or clinical contraindication to the formulary agents

DURATION OF APPROVAL:
Initial authorization: as clinically appropriate based on indication – up to 6 months, 12 months for Prophylaxis of Candida Infections in patients undergoing hematopoietic stem cell transplantation
Continuation of Therapy: for up to 6 months as clinicall

QUANTITY:
Adults: 150 mg/day IV. Geriatric: 150 mg/day IV. Adolescents: > 30 kg: 2.5 mg/kg/day IV (Max: 150 mg/day); <= 30 kg: 3 mg/kg/day IV. Children: > 30 kg: 2.5 mg/kg/day IV (Max: 150 mg/day); <= 30 kg: 3 mg/kg/day IV. Infants: >= 4 months: 3 mg/kg/day IV; < 4 months: Safety and efficacy have not been established; however, doses up to 4 mg/kg/day IV have been used off-label for Candida infections. Neonates: Term Neonates: Safety and efficacy have not been established; however, doses up to 10 mg/kg/day IV have been used off-label. Premature Neonates: Safety and efficacy have not been established; however, doses up to 15 mg/kg/day IV have been used off-label.

PRESCRIBER REQUIREMENTS: Prescribed by or in consultation with an infectious disease specialist

AGE RESTRICTIONS: 4 months of age and older

GENDER:
Male and female

CONTINUATION OF THERAPY:
Infectious Disease clinical notes documenting medical necessity for continuation of therapy

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:
MYCAMINE is contraindicated in persons with known hypersensitivity to micafungin, any component of MYCAMINE, or other echinocandins.

OTHER SPECIAL CONSIDERATIONS: None

BACKGROUND: None

APPENDIX:

REFERENCES:
1. Elsevier Clinical Pharmacology - copyright 2018
2. DailyMed online;
3. Wolters Kluwer - UpToDate online;
4. IDSA (Infectious Diseases Society of America) online - Practice Guidelines