



Effective Date: 07/01/2016
Last P&T Approval/Version: 01/26/2022
Next Review Due By: 01/2023
Policy Number: C17928-A

Candidas (caspofungin)

PRODUCTS AFFECTED

Candidas (caspofungin)

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:

Empirical therapy for presumed fungal infections in febrile, neutropenic patients, Treatment of candidemia and the following Candida infections: intraabdominal abscesses, peritonitis and pleural space infections, Treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies, Treatment of esophageal candidiasis, prophylaxis of candida infection in neutropenic cancer patients at substantial risk; chronic disseminated (hepatosplenic) Candidiasis, Candidiasis, intravascular infections; oropharyngeal (refractory disease) Candidiasis; osteoarticular Candidiasis

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

A. FOR ALL INDICATIONS:

1. Documentation member has an infection caused by or strongly suspected to be caused by a type

Drug and Biologic Coverage Criteria

of pathogen and site of infection within the FDA label or compendia supported.

AND

2. Documentation of inadequate treatment response, intolerance, contraindication, or non-susceptibility to a first-line antibiotic treatment- PREFERRED oral Fluconazole, IV voriconazole, IV amphotericin (if diagnostically appropriate)
3. FOR IV REQUESTS ONLY: Prescriber provides medical rationale for the inability of the member

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
AND
2. Documentation of no 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 rational for continued medical necessity is provided[DOCUMENTATION REQUIRED]

DURATION OF APPROVAL:

Initial authorization: as clinically appropriate based on indication – up to 6 months, 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 within initial request and reauthorization requests]

AGE RESTRICTIONS:

3 months of age and older

QUANTITY:

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

MAXIMUM DOSAGE LIMITS: Adults 70 mg/day IV; doses up to 150 mg/day IV have been recommended for cardiovascular infections.

Geriatric 70 mg/day IV; doses up to 150 mg/day IV have been recommended for cardiovascular infections.

Adolescents 70 mg/m²/day IV, not to exceed 70 mg IV. Children 70 mg/m²/day IV, not to exceed 70 mg IV.

Infants ≥ 3 months: 70 mg/m²/day IV, not to exceed 70 mg IV. < 3 months: Safety and efficacy have not been established; however, doses up to 25 mg/m²/day IV are used off-label.

Neonates Safety and efficacy have not been established; however, doses up to 25 mg/m²/day IV are used off-label.

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 and Biologic Coverage Criteria

DRUG CLASS:

Antifungal - Glucan Synthesis Inhibitors (Echinocandins)

FDA-APPROVED USES:

CANCIDAS indicated in adults and pediatric patients (3 months of age and older) for:

- Empirical therapy for presumed fungal infections in febrile, neutropenic patients.
- Treatment of candidemia and the following Candida infections: intraabdominal abscesses, peritonitis and pleural space infections.
- Treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies
- Treatment of esophageal candidiasis.

COMPENDIAL APPROVED OFF-LABELED USES:

prophylaxis of candida infection in neutropenic cancer patients at substantial risk; chronic disseminated (hepatosplenic) Candidiasis, Candidiasis, intravascular infections; oropharyngeal (refractory disease) Candidiasis; osteoarticular Candidiasis

***NOT APPLICABLE TO OUTPATIENT REVIEWS-prophylaxis against invasive candidiasis (high-risk ICU patients in units with a high rate of invasive candidiasis), empiric therapy (non-neutropenic ICU patients)

APPENDIX

APPENDIX:

None

BACKGROUND AND OTHER CONSIDERATIONS

BACKGROUND:

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

(caspofungin) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy

CANCIDAS is contraindicated in patients with known hypersensitivity (e.g., anaphylaxis) to any component of this product

OTHER SPECIAL CONSIDERATIONS:

Avoid concomitant use of caspofungin with cyclosporine unless the potential benefit outweighs the risk. Coadministration of caspofungin with CYP450 enzyme inducers (such as the rifamycin), or patients with hepatic disease, cholestasis, hepatitis, or jaundice may require a dose adjustment of caspofungin.

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
J0637	Caspofungin acetate, 5mg

AVAILABLE DOSAGE FORMS:

Cancidas Vial 50MG, Caspofungin Inj 50MG, Cancidas Inj 70MG,

REFERENCES

1. Cancidas (caspofungin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; April 2021
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):10-52. doi: 10.1093/cid/ciu296.
5. Villanueva A, Gotuzzo E, Arathoon EG, et al. A randomized double-blind study of caspofungin versus fluconazole for the treatment of esophageal candidiasis. Am J Med. 2002;113(4):294-299. doi:10.1016/s0002-9343(02)01191-9