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Current Effective Date: 03/07/2024
Last P&T Approval/Version: 01/31/2024
Next Review Due By: 01/2025
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. 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.

Drug and Biologic Coverage Criteria

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 a first-line 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:

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

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:

Candidas is 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.

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Drug and Biologic Coverage Criteria

- Treatment of invasive aspergillosis in patients who are refractory to or intolerant of other therapies
- Treatment of esophageal candidiasis.

Limitations of Use: Cancidas has not been studied in endocarditis, osteomyelitis, and meningitis due to Candida. Cancidas has not been approved for the treatment of oropharyngeal candidiasis (OPC). In the study that evaluated the efficacy of caspofungin in the treatment of esophageal candidiasis, patients with concomitant OPC had higher relapse rate of the OPC. Cancidas has not been studied as initial therapy for invasive aspergillosis.

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, Candidiasis prophylaxis and aspergillosis prophylaxis in high-risk patient, Pneumocystis pneumonia (PCP) salvage therapy

***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:

None

CONTRAINDICATIONS/EXCLUSIONS/DISCONTINUATION:

All other uses of Cancidas (caspofungin) are considered experimental/investigational and therefore, will follow Molina's Off-Label policy. Contraindications to Cancidas (caspofungin) include: patients with known hypersensitivity to any component of this product.

OTHER SPECIAL CONSIDERATIONS:

Avoid concomitant use of caspofungin with cyclosporine unless the potential benefit outweighs the risk of elevated liver enzymes. Coadministration of caspofungin with CYP450 enzyme inducers (such as the rifampin, efavirenz, nevirapine, phenytoin, dexamethasone, or carbamazepine), or patients with moderate hepatic impairment 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

HPCPS CODE	DESCRIPTION
J0637	Injection, caspofungin acetate, 5 mg

Drug and Biologic Coverage Criteria

AVAILABLE DOSAGE FORMS:

- Cancidas SOLR 50MG single dose vial
- Cancidas SOLR 70MG single dose vial
- Caspofungin Acetate SOLR 50MG single dose vial
- Caspofungin Acetate SOLR 70MG single dose vial

REFERENCES

1. Cancidas (caspofungin) [prescribing information]. Whitehouse Station, NJ: Merck Sharp & Dohme Corp; May 2022.
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
6. 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
7. Taplitz, R. A., Kennedy, E. B., & Flowers, C. R. (2018). Antimicrobial prophylaxis for adult patients with cancer-related immunosuppression: ASCO and IDSA Clinical Practice Guideline Update Summary. Journal of Oncology Practice, 14(11), 692-695. doi:10.1200/jop.18.00366

SUMMARY OF REVIEW/REVISIONS	DATE
REVISION- Notable revisions: Required Medical Information Continuation of Therapy	Q1 2024
REVISION- Notable revisions: Required Medical Information Continuation of Therapy Duration of Approval Quantity FDA-Approved Uses Compendial Approved Off-Labeled Uses Contraindications/Exclusions/Discontinuation Other Special Considerations Available Dosage Forms References	Q1 2023
Q2 2022 Established tracking in new format	Historical changes on file