RETIRED
FIRST COAST SERVICE OPTIONS
MAC - PART B
LOCAL COVERAGE DETERMINATION

LCD Database ID Number
L33807

Contractor Name
First Coast Service Options, Inc.

Contractor Number
09102 – Florida
09202 – Puerto Rico
09302 – Virgin Islands

Contractor Type
MAC – Part B

LCD Title
Caspofungin acetate (Cancidas®)

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CMS National Coverage Policy
Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals are italicized throughout the Local Coverage Determination (LCD). NCDs and coverage provisions in interpretive manuals are not subject to the LCD Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See § 1869 (f)(1)(A)(i) of the Social Security Act.

Unless other wise specified, italicized text represents quotation from one or more of the following CMS sources:

CMS Manual System, Pub. 100-02, Medicare Benefit Policy Manual, Chapter 15, Section 50

Primary Geographic Jurisdiction
Caspofungin acetate (Cancidas®) will be considered medically reasonable and necessary when provided to patients for the treatment of the following FDA approved indications:

- Empirical therapy for presumed fungal infections in febrile, neutropenic patients
- Treatment of Candidemia and the following Candida infections: intra-abdominal abscesses, peritonitis and pleural space infections
- Treatment of Esophageal Candidiasis
- Treatment of Invasive Aspergillosis in patients who are refractory to or intolerant of other therapies (i.e., amphotericin B, lipid formulation of amphotericin B, and/or itraconzole).

Limitations:

CANCIDAS has not been studied in endocarditis, osteomyelitis and meningitis due to Candida. Candida has not been studied as initial therapy for invasive aspergillosis.

Candida is contraindicated in patients with hypersensitivity to any component of this product.

Concomitant use of CANCIDAS with cyclosporine should be limited to patients for whom the potential benefit outweighs the potential risk.

CPT/HCPCS Codes

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
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<tr>
<td>J0637</td>
<td>Injection, caspofungin acetate, 5 mg</td>
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ICD-10 Codes that Support Medical Necessity
**B20**  
HUMAN IMMUNODEFICIENCY VIRUS [HIV] DISEASE

**B37.0**  
CANDIDAL STOMATITIS

**B37.1**  
PULMONARY CANDIDIASIS

**B37.81**  
CANDIDAL ESOPHAGITIS

**B37.89**  
OTHER SITES OF CANDIDIASIS

**B44.0**  
ASPERGILLOSIS

**D70.0-D70.9**  
NEUTROPENIA

**K20.9**  
ESOPHAGITIS, UNSPECIFIED

**R50.81**  
FEVER PRESENTING WITH CONDITIONS CLASSIFIED ELSEWHERE

**Z21**  
ASYMPTOMATIC HUMAN IMMUNODEFICIENCY VIRUS [HIV] INFECTION STATUS

*ICD-10 CM CODES D70.0-D70.9 AND R50.81 MUST BE BILLED TOGETHER FOR PATIENTS WITH THE DIAGNOSIS OF FEBRILE NEUTROPENIA*

**Diagnoses that Support Medical Necessity**

See ICD-10 codes that support medical necessity

**ICD 10 Codes that DO NOT Support Medical Necessity**

Any ICD-10 code not listed under ICD-10 codes that support medical necessity

**Diagnoses that DO NOT Support Medical Necessity**

Any ICD-10 code not listed under ICD-10 codes that support medical necessity

**Associated Information**

**Documentation Requirements**

Medical record documentation maintained by the ordering/referring physician must substantiate the medical necessity for the use of the Cancidas® by documenting the indication for which it must be administered. Any diagnostic tests (e.g., chest X-ray, sputum culture or other lab test to confirm the diagnosis of candida) must be in the medical record. Any subsequent diagnostic tests performed to monitor the patient’s response to treatment must be in the medical record. The drug name, dosage and route of administration must also be recorded. This information is normally found in the progress notes or medication administration record. These records must be available upon request.

Invasive Aspergillosis: The medical record documentation must document that the patient is refractory to or intolerant of other therapies (i.e., amphotericin B, lipid formulation of amphotericin B, and/or itraconzole) as indicated in the indications and limitation section of this LCD.

**Utilization Guidelines**

**Dosage and Frequency:**

**Empirical Therapy:** A single 70 mg loading dose should be administered on Day 1, followed by 50mg daily thereafter. Duration of treatment should be based on the patient’s clinical response. Empirical therapy should be continued until resolution of neutropenia. Patients found to have a fungal infection should be treated for a minimum of 14 days; treatment should continue for at least 7 days.
after both neutropenia and clinical symptoms are resolved. If the 50mg dose is well tolerated but does not provide an adequate clinical response, the daily dose can be increased to 70mg.

**Candidemia and other Candida Infections:** A single 70 mg loading dose should be administered on Day 1, followed by 50mg daily thereafter. Candida® should be administered by slow IV infusion over approximately 1 hour. Duration of treatment should be dictated by the patient’s clinical and microbiological response. In general, antifungal therapy should continue for at least 14 days after the last positive culture. Patients who remain persistently neutropenic may warrant a longer course of therapy pending resolution of the neutropenia.

**Esophageal Candidiasis:** The dose should be 50mg daily. Because the risk of relapse of oropharyngeal candidiasis in patients with HIV infections, suppressive oral therapy could be considered. A **70 mg loading dose has not been studied with this indication.**

**Invasive Aspergillosis:** A single 70 mg loading dose should be administered on Day 1, followed by 50mg daily thereafter. Duration of treatment should be based upon the severity of the patient’s underlying disease, recovery from immunosuppression and clinical response. The efficacy of a 70mg dose regimen in patients who are not clinically responding to the 50mg daily dose is not known.

**Sources of Information and Basis for Decision**

FCSO reference LCD number – L29109


**Start Date of Comment Period**

N/A

**End Date of Comment Period**

N/A

**Start Date of Notice Period**

04/01/2014

**Revision History**
Revision History Number: R1

Revision Number: 1
Publication: May 2017 Connection
LCR B2017-005

Explanation of revision: Based on data analysis review of the local coverage determination (LCD), it was determined that the LCD is no longer required and, therefore, is being retired. The effective date of this LCD retirement is based on date of service.

Revision Number: Original
Publication: April 2014 Connection

This LCD replaces all previous LCD versions (refer to “Sources of Information and Basis for Decision” section of the LCD) and publications on this subject to comply with ICD-10-CM based on Change Request 8112. The effective date of this LCD is based on date of service.

Related Documents

N/A

LCD Attachments

Coding Guidelines

Document formatted 03/24/2017 (MP/et)