Zinplava® (bezlotoxumab)

Definition

Zinplava is a human monoclonal antibody. It binds to Clostridium difficile toxin B, which prevents toxin B from binding to and affecting mammalian cells. It is approved to reduce recurrence of CDI in patients 18 years of age or older who are receiving antibacterial drug treatment of CDI and are at high risk for CDI recurrence. Zinplava is not indicated for the treatment of CDI. Zinplava is not an antibacterial drug and should only be used in conjunction with antibacterial drug treatment of CDI.

Length of Authorization

Coverage will be provided for 1 dose.

Dosing Limits

Max Units (per dose and over time) [Medical Benefit]:

- 10 mg/kg for 1 dose

I. INITIAL APPROVAL CRITERIA

Zinplava may be considered medically necessary if the below condition is met AND use is consistent with the medical necessity criteria that follows:

1. Clostridium difficile infection (CDI), recurrent
   a. Patient is 18 years of age or older; AND
   b. Member has a confirmed diagnosis of Clostridium difficile infection (CDI) with documentation of the following: diarrhea (passage of 3 or more loose bowel movements in 24 or fewer hours) and a positive stool test for toxigenic C. difficile from a stool sample collected no more than 7 days prior; AND
   c. Member is at high risk of CDI recurrence, defined as any of the following:
      i. Age greater than or equal to 65 years; OR
ii. Long term use of systemic antibacterial drugs (excluding standard of care antibiotics); OR
iii. History of 1 or more prior episodes of CDI within the previous 6 months; OR
iv. Immunocompromised (defined as having an active hematologic malignancy, using an antineoplastic or immunomodulating agent, using corticosteroids, having received a prior solid organ transplant, being asplenic, being neutropenic/pancytopenic, or having AIDS/immunodeficient condition); OR
v. Clinically severe CDI (as defined by a Zar score of greater than or equal to 2); OR
vi. Hypervirulent strain (ribotypes 027, 078 or 244); AND
d. Bezlotoxumab will be given in conjunction with standard of care antibiotics (Infusion will be given during the antibiotic treatment course)

Limitations/Exclusions

1) Zinplava should be used only in conjunction with antibacterial drug treatment of CDI.
2) The use of Zinplava is considered investigational when the above criteria are not met, and for all other conditions, including but not limited to first-line therapy.

II. **RENEWAL CRITERIA**

- Repeat administration of Zinplava is considered experimental and investigational.

**Dosage/Administration**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
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<tr>
<td>Clostridium difficile infection (CDI), recurrent</td>
<td>– 10 mg/kg administered as an intravenous infusion over 60 minutes as a single dose.</td>
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**Applicable Procedure Codes**

| J0565 | Injection, bezlotoxumab, 10 mg, 1 billable unit = 10 mg |

**Applicable NDCs**

| 00006-3025-00 | Ziplava single use vial; 25 mg/1 ml solution |

**Applicable Diagnosis Codes**

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<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
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<tr>
<td>A04.71-A04.72</td>
<td>Enterocolitis due to Clostridium difficile</td>
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**References**