Policy Title: Nipent (pentostatin) Non-Oncology Policy (Intravenous)

Department: PHA

Effective Date: 09/01/2020

Review Date: 8/3/2020, 5/27/2021

Purpose: To support safe, effective and appropriate use of Nipent (pentostatin).

Scope: Medicaid, Commercial, Medicare-Medicaid Plan (MMP)

Policy Statement:
Nipent (pentostatin) is covered under the Medical Benefit when used within the following guidelines for non-oncology indications. Use outside of these guidelines may result in non-payment unless approved under an exception process. For oncology indications, please refer to Nipent Oncology Policy.

Procedure:
Coverage of Nipent (pentostatin) will be reviewed prospectively via the prior authorization process based on criteria below.

Initial Criteria
- Adult patient (18 years or older); AND
- Documented chronic or acute graft verse host disease (GVHD) that is steroid-refractory; AND
- Must be prescribed by a hematologist or oncologist; AND
- Dose does not exceed 1.5mg/m² daily for 3 days for acute GVHD or 4mg/m² once every 2 weeks for chronic GVHD

Continuation of Therapy Criteria:
- Patient continues to meet initial criteria; AND
- Patient is tolerating treatment with absence of unacceptable toxicity from the drug.

Coverage durations:
- Initial coverage: 6 months
- Continuation of therapy coverage: 6 months
*** Requests will also be reviewed to National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) if applicable. ***

**Dosage/Administration:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute GVHD</td>
<td>1.5 mg/m² daily for 3 days; may repeat after 2 weeks if needed</td>
</tr>
<tr>
<td>Chronic GVHD</td>
<td>4 mg/m² once every 2 weeks</td>
</tr>
</tbody>
</table>

**Dosing Limits:**

<table>
<thead>
<tr>
<th>Indication</th>
<th>Maximum dose (1 billable unit = 10 mg)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acute GVHD</td>
<td>0.855 units for 3 days</td>
</tr>
<tr>
<td>Chronic GVHD</td>
<td>0.76 units per dose once every 2 weeks</td>
</tr>
</tbody>
</table>

**Investigational use:** All therapies are considered investigational when used at a dose or for a condition other than those that are recognized as medically accepted indications as defined in any one of the following standard reference compendia: American Hospital Formulary Service Drug information (AHFS-DI), Thomson Micromedex DrugDex, Clinical Pharmacology, Wolters Kluwer Lexi-Drugs, or Peer-reviewed published medical literature indicating that sufficient evidence exists to support use. Neighborhood does not provide coverage for drugs when used for investigational purposes.

**Applicable Codes:**

Below is a list of billing codes applicable for covered treatment options. The below tables are provided for reference purposes and may not be all-inclusive. Requests received with codes from tables below do not guarantee coverage. Requests must meet all criteria provided in the procedure section.

The following HCPCS/CPT code is:

<table>
<thead>
<tr>
<th>HCPCS/CPT Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>J9268</td>
<td>Injection, pentostatin, 10mg</td>
</tr>
</tbody>
</table>

**References:**