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| **Policy Title:** | Nipent (pentostatin) **Non-Oncology Policy** (Intravenous) | | |
| | | **Department:** | PHA |
| **Effective Date:** | 09/01/2020 | | |
| **Review Date:** | 8/3/2020, 5/27/2021, 03/03/2022, 02/16/2023, 12/07/2023, 01/04/2024, 05/21/2025 | | |

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

**Scope:** Medicaid, Commercial, Medicare

**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.

**Summary of Evidence:**

Nipent (penostatin) has compendium support for use in Graft-verse-Host Disease (GVHD). Its mechanism of action is selective T-cell depletion through inhibition of adenosine deaminase. This makes it a viable option in severe T-cell mediated immune responses such as GVHD. Evidence from small studies and institutional protocols supports its use in combination with other agents. A retrospective study at MD Anderson Cancer Center evaluated 60 patients with steroid-refractory active GVHD (SR-aGVHD) treated with pentostatin. Nearly half had grade 4 HGVHD, 51% had stage 3-4 lower gastrointestinal (LGI) involvement, and 22% had stage 3-4 liver involvement. The median number of pentostatin cycles administered was 3. The overall response rate (ORR) at day 28 was 33%, including 18% complete responses and 15% partial responses. Adverse events reported with Nipent including nausea/vomiting (63%), rash (43%), fatigue (42%), leukopenia (60% in Interferon-refractory patients), and infections (35% in trials).

**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/$m^2$ daily for 3 days for acute GVHD or 4mg/$m^2$ once every 2 weeks for chronic GVHD
- Medicare members who have previously received this medication within the past 365 days are not subject to Step Therapy Requirements

**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

Per §§ 42 CFR 422.101, this clinical medical policy only applies to Medicare in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

**Policy Rationale:**
Nipent was reviewed by the Neighborhood Health Plan of Rhode Island Pharmacy & Therapeutics (P&T) Committee. Neighborhood adopted the following clinical coverage criteria to ensure that its members use Nipent according to Food and Drug Administration (FDA) approved labeling and/or relevant clinical literature. Neighborhood worked with network prescribers and pharmacists to draft these criteria. These criteria will help ensure its members are using this drug for a medically accepted indication, while minimizing the risk for adverse effects and ensuring more cost-effective options are used first, if applicable and appropriate. For Medicare members, these coverage criteria will only apply in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD) criteria. Neighborhood will give individual consideration to each request it reviews based on the information submitted by the prescriber and other information available to the plan.

**Dosage/Administration:**

| **Indication** | **Dose** |
|---|---|
| Acute GVHD | 1.5 mg/$m^2$ daily for 3 days; may repeat after 2 weeks if needed |
| Chronic GVHD | 4 mg/$m^2$ once every 2 weeks |

**Dosing Limits:**

| **Indication** | **Maximum dose (1 billable unit = 10 mg)** |
|---|---|
| Acute GVHD | 0.855 units for 3 days |

| | |
|---|---|
| Chronic GVHD | 0.76 units per dose once every 2 weeks |

**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:

| HCPCS/CPT Code | Description |
|---|---|
| J9268 | Injection, pentostatin, 10mg |

References:

1. Nipent [package insert]. Lake Forest, IL Hospira, Inc; September 2024. Accessed May 2025.