

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		

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 versus 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
- MMP 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 INTEGRITY in the absence of National Coverage Determination (NCD) or Local Coverage Determination (LCD).

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; October 2021. Accessed November 2023.