CARECONTINUUM™

UTILIZATION MANAGEMENT MEDICAL POLICY

POLICY: Oncology (Injectable) – Nipent Utilization Management Medical Policy
- Nipent™ (pentostatin intravenous infusion – Hospira)

REVIEW DATE: 09/23/2026

OVERVIEW
Nipent, an adenosine deaminase inhibitor, is indicated for the treatment of untreated and alpha-interferon refractory **hairy cell leukemia** in patients with active disease, defined by clinically significant anemia, neutropenia, thrombocytopenia, or disease-related symptoms, as a single-agent.[1]

Dosing
For hairy cell leukemia the recommended dosage is Nipent 4 mg/m^2 every other week.[1]

Guidelines
Nipent is addressed in National Comprehensive Cancer Network guidelines:
- **Cutaneous Lymphoma:** Guidelines (version 2.2026 – February 13, 2026) recommend Nipent as a single agent for the subsequent treatment of disease refractory to multiple previous therapies.[2,5]
- **Hairy Cell Leukemia:** Guidelines (version 2.2027 – September 14, 2026) recommend Nipent as preferred therapy as a single agent for initial therapy.[2] Nipent is also recommended as a single agent or in combination with a rituximab product (e.g., Rituxan, biosimilars) for less than a complete response to initial therapy or relapsed disease within 2 years of complete response following initial treatment with cladribine.[2,3] Nipent is also recommended with a rituximab product for retreatment for relapse ≥ 2 years following initial treatment and for relapse ≥ 2 years following initial treatment with cladribine.
- **Graft-Versus-Host Disease:** Guidelines for Hematopoietic Cell Transplantation (version 3.2026 – July 30, 2026) recommend Nipent, in combination with corticosteroids, for acute or chronic graft-versus-host disease following no response to first-line therapy options (steroid-refractory).[2,4] Nipent is also recommended as part of a conditioning regimen for hematopoietic cell transplant.
- **T-Cell Lymphomas:** Guidelines (version 2.2026 – February 13, 2026) recommend Nipent as second-line therapy, as a single agent, for T-cell large granular lymphocytic leukemia, and in combination with Campath® (alemtuzumab intravenous infusion and subcutaneous injection) or as a single agent for T-cell prolymphocytic leukemia and hepatosplenic T-cell lymphoma.[2,6]

Safety
Nipent has a Boxed Warning for dose-limiting severe renal, liver, pulmonary, and central nervous system toxicities when used at higher than recommended doses.[1] The use of Nipent in combination with fludarabine is not recommended due to severe or fatal pulmonary toxicity.

POLICY STATEMENT
Prior Authorization is recommended for medical benefit coverage of Nipent. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required

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for evaluation and diagnosis of patients treated with Nipent as well as the monitoring required for adverse events and long-term efficacy, approval requires Nipent to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nipent is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Hairy Cell Leukemia.** Approve for 6 months if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is prescribed by or in consultation with an oncologist or hematologist.

   Dosing. Approve up to 4 mg/m^2 administered intravenously no more frequently than once every 2 weeks.

Other Uses with Supportive Evidence

2. **Graft-Versus-Host Disease.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient has steroid-refractory disease; AND
   - **B)** The medication will be used in conjunction with systemic corticosteroids; AND
     Note: Examples of corticosteroids include prednisone and methylprednisolone.
   - **C)** The medication is prescribed by or in consultation with an oncologist.

   Dosing. Approve up to 1.5 mg/m^2 administered intravenously no more frequently than three times in each 14-day cycle.

3. **Hematopoietic Cell Transplantation.** Approve for 1 month if the patient meets ALL of the following (A, B, C, and D):
   - **A)** Patient is ≥ 4 years of age; AND
   - **B)** The medication is used for reduced intensity conditioning; AND
   - **C)** The medication is used in combination with ONE of the following (i, ii, or iii):
     - **i.** Busulfan; OR
     - **ii.** Busulfan plus cyclophosphamide; OR
     - **iii.** Cyclophosphamide plus total body irradiation; AND
   - **D)** The medication is prescribed by or in consultation with an oncologist or a physician that specializes in hematopoietic cell transplantation.

   Dosing. Approve up to 4 mg/m^2 administered intravenously twice prior to hematopoietic cell transplantation.

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4. **Mycosis Fungoides/Sezary Syndrome.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   A) Patient is ≥ 18 years of age; AND
   B) Patient has relapsed or refractory disease; AND
   C) The medication is prescribed by or in consultation with an oncologist or dermatologist.

   Dosing. Approve up to 5 mg/m^2 administered intravenously no more frequently than three times in each 21-day cycle.

5. **T-Cell Lymphoma.** Approve for 6 months if the patient meets ALL of the following (A, B, and C):
   Note: Examples of T-cell lymphoma include hepatosplenic T-cell lymphoma, T-cell prolymphocytic leukemia, and T-cell large granular lymphocytic leukemia.
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following (i or ii):
      i. Patient has hepatosplenic T-cell lymphoma or T-cell prolymphocytic leukemia; OR
      ii. Patient meets BOTH of the following (a and b):
         a) Patient has T-cell large granular lymphocytic leukemia; AND
         b) Patient has progressive or refractory disease; AND
   C) The medication is prescribed by or in consultation with an oncologist or hematologist.

   Dosing. Approve up to 4 mg/m^2 administered intravenously no more frequently than once weekly.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Nipent is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Nipent intravenous infusion [prescribing information]. Lake Forest, IL: Hospira; November 2025.
2. The NCCN Drugs and Biologics Compendium. © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 18, 2026. Search term: pentostatin.
3. The NCCN Hairy Cell Leukemia Clinical Practice Guidelines in Oncology (version 2.2027 – September 14, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 18, 2026.
4. The NCCN Hematopoietic Cell Transplantation Clinical Practice Guidelines in Oncology (version 3.2026 – July 30, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 18, 2026.
5. The NCCN Cutaneous Lymphomas Clinical Practice Guidelines in Oncology (version 2.2026 – February 13, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 18, 2026.
6. The NCCN T-Cell Lymphomas Clinical Practice Guidelines in Oncology (version 2.2026 – February 13, 2026). © 2026 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on September 18, 2026.

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HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	09/11/2024
Annual Revision	**Hairy Cell Leukemia**: The requirements that the medication is used as a single agent and medication is used in combination with rituximab were removed. **Mycosis Fungoides/Sezary Syndrome**: The requirement that the medication will be used as a single agent was removed. **T-Cell Lymphoma:** T-cell large granular lymphocytic leukemia, T-cell prolymphocytic leukemia, and hepatosplenic T-cell lymphoma were moved to be addressed under T-Cell lymphoma. For T-cell large granular lymphocytic leukemia, the requirement that the medication will be used as a single agent was removed. For T-cell prolymphocytic leukemia and hepatosplenic T-cell lymphoma, the requirements that the medication is used as a single agent and that medication is used in combination with Campath were removed.	09/10/2025
Annual Revision	**Hairy Cell Leukemia:** Hematologist was added as an approved prescriber option. **T-Cell Lymphoma:** Hematologist was added as an approved prescriber option.	09/23/2026

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