Reference number(s)
4842-A

STANDARD MEDICARE PART B MANAGEMENT

NIPENT (pentostatin for injection)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Nipent is indicated as single-agent treatment for both untreated and alpha-interferon-refractory hairy cell leukemia patients with active disease as defined by clinically significant anemia, neutropenia, thrombocytopenia, or disease-related symptoms.

B. Compendial Uses

1. Relapsed or refractory hairy cell leukemia
2. T-cell large granular lymphocytic leukemia
3. T-cell prolymphocytic leukemia
4. Hepatosplenic T-cell lymphoma
5. Mycosis fungoides/Sezary syndrome
6. Graft-versus-host disease, acute or chronic
7. Chronic lymphocytic leukemia/small lymphocytic lymphoma

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request:
For hairy cell leukemia, initial requests: Lab results showing active disease (clinically significant anemia, neutropenia, thrombocytopenia, disease-related symptoms)

III. CRITERIA FOR INITIAL APPROVAL

A. Hairy Cell Leukemia

Authorization of 12 months may be granted for treatment of hairy cell leukemia when all of the following criteria are met:

1. The member has active disease as defined by one of the following clinically significant symptoms:
   i. Anemia
   ii. Neutropenia

iii. Thrombocytopenia
iv. Disease-related symptoms

2. The requested drug will be used in one of the following settings:
   i. As a single agent for any of the following:
      a. Initial therapy
      b. Less than complete response following initial treatment with cladribine or alpha-interferon
      c. Relapse within 2 years of complete response
   ii. In combination with rituximab for any of the following:
      a. Less than complete response or relapse within 2 years of complete response following initial treatment with cladribine
      b. Relapse at least 2 years following initial treatment

B. T-Cell Large Granular Lymphocytic Leukemia
Authorization of 12 months may be granted for second-line treatment of progressive or refractory T-cell large granular lymphocytic leukemia when used as a single agent.

C. T-Cell Prolymphocytic Leukemia
Authorization of 12 months may be granted for first- or second-line treatment of T-cell prolymphocytic leukemia when all of the following criteria are met:
1. The member has symptomatic disease
2. The requested drug will be used in combination with alemtuzumab

D. Hepatosplenic T-Cell Lymphoma
Authorization of 12 months may be granted for treatment of hepatosplenic T-cell lymphoma when any of the following criteria are met:
1. The requested drug will be used in combination with alemtuzumab as first-line therapy or as alternate induction after first-line therapy
2. The requested drug will be used as a single agent for refractory disease

E. Mycosis Fungoides/Sezary Syndrome
Authorization of 12 months may be granted for treatment of refractory mycosis fungoides/Sezary syndrome when used as a single agent.

F. Graft-Versus-Host Disease
Authorization of 12 months may be granted for treatment of acute or chronic graft-versus-host disease (GVHD) in combination with systemic corticosteroids for steroid-refractory disease.

G. Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
Authorization of 12 months may be granted for treatment of chronic lymphocytic leukemia/small lymphocytic lymphoma (CLL/SLL) when used as a component of PCR (pentostatin, cyclophosphamide, and rituximab).

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
1. The member is currently receiving therapy with the requested medication

2. The requested medication is being used to treat an indication enumerated in Section III
3. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen AND
   ii. No evidence of disease progression while on the current regimen.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:

1. The prescribing information for Nipent.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: Hairy cell leukemia
4. NCCN Guideline: Hematopoietic cell transplantation
5. NCCN Guideline: Primary cutaneous lymphomas
6. NCCN Guideline: T-cell lymphomas

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Nipent are covered in addition to the following:

1. Relapsed or refractory hairy cell leukemia
2. T-cell large granular lymphocytic leukemia
3. T-cell prolymphocytic leukemia
4. Hepatosplenic T-cell lymphoma
5. Mycosis fungoides/Sezary syndrome
6. Graft-versus-host disease, acute or chronic
7. Chronic lymphocytic leukemia/small lymphocytic lymphoma

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

Support for using Nipent to treat hairy cell leukemia, T-cell large granular lymphocytic leukemia, T-cell prolymphocytic leukemia, hepatosplenic T-cell lymphoma, mycosis fungoides/Sezary syndrome, and graft-versus-host disease can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using Nipent to treat Mycosis fungoides, graft-versus-host disease, and chronic lymphocytic leukemia/small lymphocytic lymphoma can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VII. REFERENCES

Reference number(s)
4842-A

1. Nipent [package insert]. Lake Forest, IL: Hospira, Inc; November 2019.
2. The NCCN Drugs & Biologics Compendium® © 2022 National Comprehensive Cancer Network, Inc. Available at: https://www.nccn.org. Accessed June 14, 2022.
3. Nipent. Micromedex Solutions. Greenwood Village, CO: Truven Health Analytics. http://micromedex.com/. November 6, 2021. Accessed June 14, 2022.