Medical Drug Clinical Criteria

Subject:	Decnupaz (pivekimab sunirine-pvzy)		
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Overview

This document addresses the use of Decnupaz (pivekimab sunirine-pvzy). Decnupaz is a CD123-directed antibody drug conjugate (ADC) primarily used to treat blastic plasmacytoid dendritic cell neoplasm (BPDCN). BPDCN is an aggressive and rare disease of bone marrow and blood that can affect multiple organs, including the lymph nodes and the skin. It often presents as leukemia or evolves into acute leukemia. ADCs deliver cell death-inducing agents directly to the cells expressing a specific protein. CD123 is a protein overexpressed in BPDCN. Decnupaz use leads to apoptosis and cell death.

Decnupaz efficacy was evaluated in the CADENZA (NCT03386513) trial that included 33 patients with treatment-naïve BPDCN and 51 patients with relapsed or refractory BPDCN with efficacy based on rate of complete remission or clinical complete remission.

Decnupaz has a black box warning for hepatotoxicity, including hepatic veno-occlusive disease (VOD). Recommendations are to closely monitor for signs and symptoms of VOD including liver tests and total bilirubin prior to each dose. Delayed administration is recommended for liver test elevation. Discontinuation is recommended for patients who experience VOD.

Definitions and Measures

Complete Response (CR): The disappearance of all signs of cancer as a result of treatment; also called complete remission; does not indicate the cancer has been cured.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Decnupaz (pivekimab sunirine-pvzy)

Requests for Decnupaz (pivekimab sunirine-pvzy) may be approved if the following criteria are met:

I. Individual is under 19 years of age;

OR

II. Individual has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN).

Requests for Decnupaz (pivekimab sunirine-pvzy) may not be approved when the above criteria are not met and for all other indications.

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS	
C9313	Injection, pivekimab sunirine-pvzy, 0.01 mg [Decnupaz]
J9999	Not otherwise classified, antineoplastic drugs [when specified as Decnupaz (pivekimab-sunirine-pvzy)]

ICD-10 Diagnosis	
C86.40	Blastic NK-cell lymphoma not having achieved remission [blastic plasmacytoid dendritic cell neoplasm (BPDCN)]

Document History

New: 06/08/2026
Document History:

- 09/08/2026 – Coding Update: Removed HCPCS NOC C9399 effective 9/30/26 and added C9313 effective 10/1/26.
- 06/08/2026 –Select Review: New clinical criteria for Decnupaz. Coding Reviewed: Added HCPCS NOC C9399, J9999, and ICD-10-CM C86.40.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 2, 2026.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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