Decnupaz® (pivekimab sunirine-pvzy)
(Intravenous)

Document Number: IC-0861

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I. Length of Authorization

- Initial: Prior authorization validity will be provided initially for 6 months (180 days).
- Renewal: Prior authorization validity may be renewed every 6 months (180 days) thereafter.

II. Dosing Limits

Max Units (per dose and over time) [HCPCS Unit]:

- 6 mg (3 vials) every 21 days

III. Initial Approval Criteria [1]

Prior authorization validity is provided in the following conditions:

- Member is at least 18 years of age; **AND**

Universal Criteria [1,2]

- Member has CD123-positive/expressing disease *(Note: Patients who received prior CD123-targeting agents must still have blasts with detectable CD123 expression)*; **AND**
- Used as single agent therapy; **AND**
- Member will be monitored for severe infusion-related reactions, hypersensitivity reactions, and new or worsening edema; **AND**
- Member does not have a history of hepatic veno-occlusive disease (VOD) and will undergo close monitoring for signs and symptoms of VOD, including liver function testing (e.g., ALT, AST, total bilirubin) prior to each dose; **AND**
- Member does not have active central nervous system (CNS) disease involvement (member may be receiving prophylactic intrathecal [IT] chemotherapy); **AND**

Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) † ‡ Φ [1-5]

- Member must have a definitive diagnosis of BPDCN; **AND**
  - Used as first-line therapy in treatment-naïve members who have de novo disease; **OR**
  - Used as treatment for relapsed/refractory disease

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

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IV. Renewal Criteria [1-7]

Prior authorization validity may be renewed based on the following criteria:

- Member continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: severe hepatotoxicity including VOD, severe infusion-related reactions, severe edema, severe hypersensitivity reactions, etc.; **AND**
- Disease stabilization or improvement as evidenced by a complete response [CR] *(i.e., morphologic, cytogenetic or molecular complete response)* or clinical complete response [CRc] (*i.e., complete response with residual skin abnormality not indicative of active disease*)

V. Dosage/Administration [1]

Indication	Dose
BPDCN	The recommended dose of Decnupaz in adult patients with BPDCN is 0.045 mg/kg intravenously over approximately 15-30 minutes once every 3 weeks (21-day cycle) until disease progression or unacceptable toxicity. Calculate the dose based on the patient's actual body weight.

VI. Billing Code/Availability Information

HCPCS Code:

- J9999 – Not Otherwise Classified, antineoplastic drugs
- C9399 – Unclassified drug or biologicals *(Hospital Out-Patient Use)*

NDC:

- Decnupaz 2 mg lyophilized powder for injection in a single-dose vial: 00074-0282-xx

VII. References

1. Decnupaz [package insert]. North Chicago, IL; AbbVie, Inc.; May 2026. Accessed June 2026.
2. Pemmaraju N, Marconi G, Montesinos P, et al. Pivekimab Sunirine in Blastic Plasmacytoid Dendritic Cell Neoplasm. J Clin Oncol. 2026 Apr;44(10):861-873. doi: 10.1200/JCO-25-02083. Epub 2026 Feb 11.
3. Daver NG, Montesinos P, DeAngelo DJ, et al. Pivekimab sunirine (IMGN632), a novel CD123-targeting antibody-drug conjugate, in relapsed or refractory acute myeloid leukaemia: a phase 1/2 study. Lancet Oncol. 2024 Mar;25(3):388-399. doi: 10.1016/S1470-2045(23)00674-5.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) pivekimab sunirine. National Comprehensive Cancer Network, 2026. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the

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National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed June 2026.

5. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Acute Myeloid Leukemia Version 3.2026. National Comprehensive Cancer Network, 2026. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Guidelines, go online to NCCN.org. Accessed June 2026.

Appendix A – Non-Quantitative Treatment Limitations (NQTL) Factor Checklist

Non-quantitative treatment limitations (NQTLs) refer to the methods, guidelines, standards of evidence, or other conditions that can restrict how long or to what extent benefits are provided under a health plan. These may include things like utilization review or prior authorization. The utilization management NQTL applies comparably, and not more stringently, to mental health/substance use disorder (MH/SUD) Medical Benefit Prescription Drugs and medical/surgical (M/S) Medical Benefit Prescription Drugs. The table below lists the factors that were considered in designing and applying prior authorization to this drug/drug group, and a summary of the conclusions that Prime's assessment led to for each.

Factor	Conclusion
Indication	Yes: Consider for PA
Safety and efficacy	Yes: Consider for PA
Potential for misuse/abuse	No: PA not a priority
Cost of drug	Yes: Consider for PA

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C86.40	Blastic NK-cell lymphoma not having achieved remission

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

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Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC

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