

Clinical Policy: Pivekimab Sunirine-pvzy (Decnupaz)

Reference Number: PA.CP.PHAR.785

Effective Date: 08/2026

Last Review Date: 07/2026

Description

Pivekimab sunirine-pvzy (Decnupaz[™]) is a CD123-directed antibody and alkylating agent conjugate.

FDA Approved Indication(s)

Decnupaz is indicated for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness[®] that Decnupaz is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Blastic Plasmacytoid Dendritic Cell Neoplasm (must meet all):

1. Diagnosis of BPDCN;
2. Prescribed by or in consultation with an oncologist;
3. Age $\geq$ 18 years;
4. Prescribed as a single agent;
5. Member does not have active central nervous system (CNS) disease;
6. Documentation of member's current body weight (in kg);
7. Request meets one of the following (a or b):
 - a. Dose does not exceed 0.045 mg/kg every 3 weeks;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Blastic Plasmacytoid Dendritic Cell Neoplasm (must meet all):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;
2. Member is responding positively to therapy;
3. Documentation of member's current body weight (in kg);
4. If request is for a dose increase, request meets one of the following (a or b):

- a. New dose does not exceed 0.045 mg/kg every 3 weeks;
- b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.

Approval duration: Duration of request or 12 months (whichever is less); or

2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

BPDCN: blastic plasmacytoid dendritic cell neoplasm

CNS: central nervous system

FDA: Food and Drug Administration

VOD: veno-occlusive disease

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none
- Boxed warning(s): hepatotoxicity, including hepatic veno-occlusive disease (VOD) (also known as sinusoidal obstruction syndrome)

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
BPDCN	0.045 mg/kg IV every 3 weeks until disease progression or unacceptable toxicity	0.045 mg/kg every 3 weeks

VI. Product Availability

Single-dose vial for injection: 2 mg

VII. References

1. Decnupaz Prescribing Information. North Chicago, IL: AbbVie Inc; May 2026. Available at: https://www.rxabbvie.com/pdf/decnupaz_pi.pdf. Accessed June 9, 2026.
2. Pemmaraju N, Marconi G, Montesinos P, et al. Pivekimab sunirine in blastic plasmacytoid dendritic cell neoplasm. J Clin Oncol 2026;44:861-873.

3. ClinicalTrials.gov. Study of IMG632 in patients with untreated BPDCN and relapsed/refractory BPDCN. December 12, 2024 Available at: <https://clinicaltrials.gov/ct2/show/NCT03386513>. Accessed June 9, 2026.
4. National Comprehensive Cancer Network Guidelines. Acute Myeloid Leukemia Version 3. 2026. Available at: https://www.nccn.org/professionals/physician_gls/pdf/aml.pdf. Accessed June 9, 2026.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
C9399	Unclassified drugs or biologicals
J9999	Not otherwise classified, antineoplastic drugs

Reviews, Revisions, and Approvals	Date
Policy created	07/2026