Medical Policy

Utilization Management and Clinical Medical Policy

Policy Name:	Policy Number:	Scope:	Origination Date:	Effective Date:
pivekimab sunirine-pvzy (Decnupaz™)	**MP-RX-FP-190-26**	☒ MMM MA ☒ MMM MultiHealth	**7/22/2026**	**7/22/2026**
			Last Review Date: **7/22/2026**	**Frequently Revision:** **Annual**

Service Category:

☐ Anesthesia
☐ Surgery
☐ Radiology Procedures
☐ Pathology and Laboratory Procedures
☐ Medicine Services and Procedures
☐ Evaluation and Management Services
☐ DME/Prosthetics or Supplies
☒ Other: Part B Drugs

Service Description:

This document addresses the use of pivekimab sunirine-pvzy (Decnupaz™), a CD123-directed antibody and alkylating agent conjugate indicated for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

Background Information:

Blastic plasmacytoid dendritic cell neoplasm (BPDCN) is a rare and aggressive hematologic malignancy derived from plasmacytoid dendritic cell precursors. BPDCN predominantly affects older adults and is more common in males. Most patients present with cutaneous lesions, with or without leukemic dissemination. Disease may also involve the bone marrow, peripheral blood, lymph nodes, spleen, and central nervous system (CNS), and some patients may present with leukemia without skin involvement.

Diagnosis of BPDCN is based on characteristic morphology and immunophenotypic findings. Tumor cells typically express CD123, CD4 and/or CD56, along with one or more plasmacytoid dendritic cell-associated antigens by flow cytometry and/or histochemistry. Evaluation generally includes bone marrow examination and lumbar puncture to assess for CNS involvement, as management may be guided by the presence or absence of CNS disease.

Decnupaz (pivekimab sunirine-pvzy) is a CD123-directed antibody-drug conjugate indicated for the treatment of adult patients with BPDCN. Pivekimab sunirine-pvzy binds to CD123-expressing cells and, after intracellular processing, releases a cytotoxic payload that leads to DNA alkylation, DNA damage, apoptosis, and cell death. The recommended dose is 0.045 mg/kg administered as an intravenous infusion over approximately 15 to 30 minutes once every 3 weeks until disease progression or unacceptable toxicity.

The approval of Decnupaz was supported by the pivotal CADENZA trial (NCT03386513), which enrolled both treatment-naïve and relapsed/refractory BPDCN patients. Diagnosis for trial enrollment required pathologic and immunophenotypic confirmation, including CD123 expression. Reported efficacy outcomes were:

- Treatment-naïve patients: 69.7% complete response/complete response with incomplete count recovery (CR/CRc), with 39.4% of patients successfully bridged to stem cell transplant.
- Relapsed/refractory patients: 15.7% CR/CRc, with 11.8% bridged to stem cell transplant.

Decnupaz carries a boxed warning for hepatotoxicity, including hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome, which may be severe or fatal. Patients should be closely monitored for signs and symptoms of VOD, including elevations in liver tests, hepatomegaly, rapid weight gain, and ascites. Liver tests, including ALT, AST, and total bilirubin, should be monitored prior to each dose. Decnupaz should be permanently discontinued in patients who experience VOD. Additional clinically relevant warnings and

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precautions include infusion-related reactions, edema and fluid retention, sulfite allergic reactions, embryo-fetal toxicity, and avoidance of use in patients with moderate to severe renal or hepatic impairment.

As of this policy's effective date, no NCCN Guidelines category recommendation has been published for pivekimab sunirine-pvzy in BPDCN. Given the recency of approval and the ultra-rare nature of the indication, the CADENZA trial and current FDA labeling constitute the primary evidentiary basis for this policy's medical necessity criteria, pending future guideline updates.

Approved Indications

A. Treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

Other Uses

A. None.

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Medical Necessity Guidelines:

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.

pivekimab sunirine-pvzy *(Decnupaz™)*

A. Criteria For Initial Approval (*Provider must submit documentation [such as office chart notes, lab results, pathology reports, imaging studies, and any other pertinent clinical information] supporting the patient's diagnosis for the drug and confirming that the patient has met **all** approval criteria.)*

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

i. Individual is 18 years of age or older; **AND**
ii. Individual has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (BPDCN); **AND**
iii. Documentation is provided that the diagnosis has been confirmed by pathology and immunophenotypic testing consistent with BPDCN, including CD123 expression and other supportive plasmacytoid dendritic cell markers, as applicable.

B. Criteria For Continuation of Therapy

i. MMM considers continuation of Decnupaz (pivekimab sunirine-pvzy) therapy medically necessary in members requesting reauthorization for an indication listed in Section A Above (Criteria for Initial Approval) when there is no evidence of unacceptable toxicity or disease progression while on the current regimen. The following information should be submitted for reauthorization:
    A. A current oncology note documenting the patient's response to treatment showing no progression of disease.
    B. Current imaging studies and other objective measures, as appropriate, showing no progression of disease when compared with previous results.

C. Authorization Duration

i. Initial Approval Duration: Up to 6 months
ii. Reauthorization Approval Duration: Up to 6 months

D. Conditions Not Covered

Any other use is considered experimental, investigational, or unproven, including the following (this list may not be all inclusive):

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i. Requests for Decnupaz (pivekimab sunirine-pvzy) may not be approved when the above criteria (Section A: Criteria for Initial Approval) are not met and for all other indications.

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Limits or Restrictions:

A. Therapeutic Alternatives

The list below includes preferred alternative therapies recommended in the approval criteria and may be subject to prior authorization.

i. N/A

B. Quantity Limitations

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines. The chart below includes dosing recommendations as per the FDA-approved prescribing information.

Drug	Recommended Dosing/Limit
Decnupaz (pivekimab sunrine-pvzy) injection 2 mg single-dose vial	• 0.045 mg/kg once every 3 weeks until disease progression or unacceptable toxicity ○ Dose should be calculated using the patient's actual body weight.
Exceptions	
• Avoid use of Decnupaz in moderate to severe hepatic and renal impairment.	

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Codes Information:

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Benefit coverage for health services is determined by the member specific benefit plan document and applicable laws that may require coverage for a specific service. The inclusion of a code does not imply any right to reimbursement or guarantee claim payment. Other Policies and Guidelines may apply.

ICD-10 Diagnostic Codes:

Codes	Description
C86.4	Blastic plasmacytoid dendritic cell neoplasm

HCPCS Codes:

Codes	Description
J3490	Unclassified drug [when specified as Decnupaz (pivekimab sunrine-pvzy)]
J3590	Unclassified biologics [when specified as Decnupaz (pivekimab sunrine-pvzy)]
J9999	Antineoplastic drugs that are not otherwise classified [when specified as Decnupaz (pivekimab sunrine-pvzy)]
C9399	Unclassified drugs or biologics [when specified as Decnupaz (pivekimab sunrine-pvzy)]

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Reference Information:

1. AbbVie Inc. DECNUPAZ™ (pivekimab sunirine-pvzy) for injection, for intravenous use: Prescribing Information.AbbVie Inc.; revised May 2026. Accessed July 2, 2026. https://www.rxabbvie.com/pdf/decnupaz_pi.pdf
2. AbbVie Inc. DECNUPAZ™ (pivekimab sunirine-pvzy) Billing and Coding Guide. AbbVie Inc.; revised May 2026. Accessed July 2, 2026. https://www.decnupazhcp.com/content/dam/decnupazhcp/pdfs/DECNUPAZ-Billing-and-Coding-Guide.pdf
3. ClinicalTrials.gov. Trial of Pivekimab Sunirine (IMGN632) in Patients With CD123+ Hematologic Malignancies (CADENZA). Identifier: NCT03386513. Bethesda, MD: National Library of Medicine; updated 2026.
4. Pemmaraju N, Marconi G, Montesinos P, et al. Pivekimab sunirine in blastic plasmacytoid dendritic cell neoplasm. *J Clin Oncol*. 2026;44(10):861-873. doi:10.1200/JCO-25-02083
5. UpToDate. Pivekimab sunirine: Drug information. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed July 2, 2026. https://www.uptodate.com/contents/pivekimab-sunirine-drug-information
6. UpToDate. Blastic plasmacytoid dendritic cell neoplasm. In: Post TW, ed. UpToDate. Waltham, MA: UpToDate Inc. Accessed July 2, 2026. https://www.uptodate.com/contents/blastic-plasmacytoid-dendritic-cell-neoplasm
7. U.S. Food and Drug Administration. FDA approves pivekimab sunirine-pvzy for blastic plasmacytoid dendritic cell neoplasm, an ultra-rare hematologic malignancy. Published May 27, 2026. Accessed July 2, 2026. https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-pivekimab-sunirine-pvzy-blastic-plasmacytoid-dendritic-cell-neoplasm-ultra-rare

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

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Policy History:

Type of Review	Summary of Changes	P&T Approval Date	UM/CMPC Approval Date
Policy Inception	New Policy creation	7/13/2026	7/22/2026