



**BlueCross  
BlueShield**

Federal Employee Program.

Blue Cross Blue Shield Association  
750 9th St NW, Suite 900  
Washington, D.C. 20001  
1-800-624-5060  
Fax 1-877-378-4727

5.21.255

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| <b>Section:</b>    | Prescription Drugs    | <b>Effective Date:</b>       | October 1, 2026 |
| <b>Subsection:</b> | Antineoplastic Agents | <b>Original Policy Date:</b> | July 17, 2026   |
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**Last Review Date:** September 17, 2026

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## Decnupaz

### Description

#### Decnupaz (pivekimab sunirine-pvzy)

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#### Background

Decnupaz (pivekimab sunirine-pvzy) is a CD123 (alpha-subunit of the interleukin-3 receptor)-directed antibody-drug conjugate (ADC). The antibody is a humanized anti-CD123 IgG1. Decnupaz binds to CD123 expressing cells and upon intracellular processing releases a cell membrane-permeable payload, FGN849, leading to DNA alkylation, single-strand DNA breaks, apoptosis, and cell death (1).

#### Regulatory Status

FDA-approved indication: Decnupaz is a CD123-directed antibody and alkylating agent conjugate indicated for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN) (1).

Decnupaz has a boxed warning for hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD), also known as sinusoidal obstruction syndrome. Closely monitor patients for signs and symptoms of VOD including elevations in liver tests, hepatomegaly, rapid weight gain, and ascites. Monitor liver tests, including ALT, AST, and total bilirubin, prior to each dose of Decnupaz. Delay Decnupaz dosage for liver test elevations. Permanently discontinue Decnupaz for patients who experience VOD (1).

Decnupaz has been associated with infusion-related reactions (IRR), edema, and sulfite allergic reactions. Premedicate with corticosteroids the day before the infusion and premedicate with corticosteroids, antihistamine, and an antipyretic prior to Decnupaz infusion. Monitor for the

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development of edema and fluid retention during treatment. Decnupaz contains sodium metabisulfite, a sulfite that may cause allergic type reactions (1).

Decnupaz can cause fetal harm when administered to a pregnant patient. Advise females of reproductive potential to use effective contraception during treatment with Decnupaz and for 7 months after the last dose. Advise male patients with female partners of reproductive potential to use effective contraception during treatment with Decnupaz, and for 4 months after the last dose (1).

FGN849 is a substrate of CYP3A. Concomitant use of Decnupaz with a strong and moderate CYP3A inhibitor may increase unconjugated FGN849 exposure, which may increase the risk of Decnupaz adverse reactions (1).

The safety and effectiveness of Decnupaz in pediatric patients less than 18 years of age have not been established (1).

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#### Related policies

Elzonris

[Policy](#)

*This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.*

Decnupaz may be considered **medically necessary** if the conditions indicated below are met.

Decnupaz may be considered **investigational** for all other indications.

### Prior-Approval Requirements

**Age** 18 years of age or older

#### Diagnosis

Patient must have the following:

Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

**AND ALL** of the following:

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1. Prescriber agrees to monitor liver function tests (LFTs), including ALT, AST, and total bilirubin prior to each dose of Decnupaz
2. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Decnupaz and for 7 months after the last dose
3. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Decnupaz and for 4 months after the last dose

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## Prior – Approval *Renewal* Requirements

**Age** 18 years of age or older

### Diagnosis

Patient must have the following:

Blastic plasmacytoid dendritic cell neoplasm (BPDCN)

**AND ALL** of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor liver function tests (LFTs), including ALT, AST, and total bilirubin prior to each dose of Decnupaz
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Decnupaz and for 7 months after the last dose
4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Decnupaz and for 4 months after the last dose

### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

**Duration** 12 months

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### Prior – Approval *Renewal* Limits

Same as above

### Rationale

#### Summary

Decnupaz (pivekimab sunirine-pvzy) is a CD123-directed antibody and alkylating agent conjugate indicated for the treatment of blastic plasmacytoid dendritic cell neoplasm (BPDCN). Decnupaz has a boxed warning for hepatotoxicity, including severe or fatal hepatic veno-occlusive disease (VOD). Decnupaz has been associated with infusion-related reactions (IRR), edema, sulfite allergic reactions, and embryo-fetal toxicity. The safety and effectiveness of Decnupaz in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Decnupaz while maintaining optimal therapeutic outcomes.

#### References

1. Decnupaz [package insert]. Chicago, IL: AbbVie, Inc.; May 2026.
2. NCCN Drugs & Biologics Compendium® Pivekimab sunirine-pvzy 2026. National Comprehensive Cancer Network, Inc. Accessed on July 16, 2026.

### Policy History

| Date           | Action                             |
|----------------|------------------------------------|
| July 2026      | Addition to PA                     |
| September 2026 | Annual review and reference update |

### Keywords

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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 17, 2026 and is effective on October 1, 2026.