

## TX CLINICAL CRITERIA & PROCEDURE

|                                                          |                                                                                 |
|----------------------------------------------------------|---------------------------------------------------------------------------------|
| <b>CRITERIA NAME:</b> Pivekimab sunirine-pvzy (Decnupaz) | <b>CRITERIA ID:</b> TX.CC.PHAR.63                                               |
| <b>BUSINESS UNIT:</b> Superior HealthPlan                | <b>FUNCTIONAL AREA:</b> Pharmacy                                                |
| <b>EFFECTIVE DATE:</b> 10/01/2026                        | <b>PRODUCT(S):</b> STAR, STAR+PLUS, STAR HEALTH, STAR KIDS, CHIP, CHIP Perinate |
| <b>REVIEWED/REVISED DATE:</b> N/A                        | <b>REGULATOR MOST RECENT APPROVAL DATE(S):</b> N/A                              |

### CRITERIA STATEMENT:

The purpose of this clinical criteria is to provide a guide to medical necessity reviews for pivekimab sunirine-pvzy (Decnupaz).

### PURPOSE:

Consistent with the regulation at 42 CFR Section 438.210 and 42 CFR Section 457.1230(d), services covered under managed care contracts, including clinician-administered drugs, must be furnished in an amount, duration, and scope that is no less than the amount, duration, and scope for the same services specified in the state plan. While MCOs may place appropriate limits on drugs, MCOs may not use a standard for determining medical necessity that is more restrictive than what is used in the state plan, i.e., developed by the Vendor Drug Program. For example, if a member is denied a clinician administered drug in managed care because of the MCO's prior authorization criteria but would have received the drug under the criteria specified in the state plan, then the MCO's prior authorization criteria would violate the amount, duration, and scope requirements cited above. HHSC intends to amend the Managed Care Contracts at the next opportunity to include this requirement. This same standard applies to CHIP formulary and CAD coverage.

Refer to the Outpatient Drug Services Handbook of the Texas Medicaid Provider Procedure Manual for more details on the clinical criteria and prior authorization requirements.

### SCOPE:

Superior HealthPlan (SHP) Pharmacy team, Centene Pharmacy Services (CPS)

### DEFINITIONS:

CPS = Centene Pharmacy Services

MCO = Managed Care Organization

SHP = Superior HealthPlan

UM = Utilization Management

VOD = Veno-occlusive disease

### POLICY:

It is the policy of Superior HealthPlan and Centene Pharmacy Services to follow state guidance for medical necessity review of Decnupaz; procedure code: C9313.

### *Description/Mechanism of Action:*

Decnupaz is a CD123-directed antibody and alkylating agent conjugate.

### *FDA Approved Indications:*

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

*Formulations:*

Decnupaz is available as 2 mg of Decnupaz as a lyophilized cake in a single-dose vial.

**PROCEDURE:**

Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria.

**I. Initial Approval Criteria:**

**A. Blastic plasmacytoid dendritic cell neoplasm (BPDCN) (must meet all):**

1. The client is 18 years or older.
2. The client has a diagnosis of blastic plasmacytoid dendritic cell neoplasm (diagnosis code C86.4) excluding acute promyelocytic leukemia (APL, FAB, M3).
3. The client has a CD-123 positive/expressing disease.
4. Provider attestation client has adequate baseline hepatic function and liver function test, including aspartate aminotransferase (AST), alanine aminotransferase (ALT), and total bilirubin are within normal limits.
5. Provider attestation to monitor patient's hepatic function prior to each course of therapy to mitigate the risk of severe or fatal VOD and to closely monitor for signs and symptoms of VOD including elevations in liver tests, hepatomegaly, rapid weight gain, and ascites. Therapy should be delayed with liver test elevations and permanently discontinued in patients who experience VOD.

**Approval duration: 12 months**

**II. Continued Therapy:**

**A. Blastic plasmacytoid dendritic cell neoplasm (BPDCN) (must meet all):**

1. The client continues to meet initial approval criteria
2. The client has previously received treatment with Decnupaz with absence of adverse drug reactions or drug toxicity.
3. The client has a positive clinical response demonstrated by disease stabilization.

**Approval duration: 12 months**

**REFERENCES:**

Texas Medicaid Provider Procedures Manual: Outpatient Drug Services Handbook

**ATTACHMENTS:**

**REVISION LOG**

| REVISION TYPE | REVISION SUMMARY | DATE APPROVED & PUBLISHED |
|---------------|------------------|---------------------------|
| New Policy    | N/A              | 10/01/2026                |

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