



**OncoEMR®**

## Order set instructions for DECNUPAZ™ (pivekimab sunirine-pvzy)

### INDICATION

DECNUPAZ™ (pivekimab sunirine-pvzy) is indicated for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

### SELECT IMPORTANT SAFETY INFORMATION

#### **BOXED WARNING: HEPATOTOXICITY, INCLUDING HEPATIC VENO-OCCLUSIVE DISEASE (VOD) (ALSO KNOWN AS SINUSOIDAL OBSTRUCTION SYNDROME)**

- VOD, a severe form of hepatotoxicity, has been reported in patients with BPDCN treated with DECNUPAZ, including severe or fatal hepatic VOD.
- Closely monitor for signs and symptoms of VOD. Monitor liver tests and total bilirubin prior to each dose.
- Discontinue DECNUPAZ for patients who experience VOD.

**Additional Warnings and Precautions:** Infusion-related reactions, edema, sulfite allergic reactions, and embryo-fetal toxicity.

**Please see full Important Safety Information, including BOXED WARNING, on pages 6 and 7. Please see full Prescribing Information.**

# Overview

## TABLE OF CONTENTS

Uses and Limitations.....	2
Instructions.....	3
Indication and Important Safety Information.....	6

## USES AND LIMITATIONS

These instructions are specifically related to including DECNUPAZ™ (pivekimab sunirine-pvzy) for its approved indication in the OncoEMR electronic health record (EHR) system. These instructions are suggestions only and are not meant to replace your institutional expertise, guidance, or independent clinical judgment. These instructions are not appropriate for other conditions, treatments, therapeutic areas, or for other EHR systems.

- Any questions should be directed to the appropriate internal EHR team or vendor
- The Customers (ie, practice, medical group, IDN, Health System) shall be solely responsible for implementing, testing, and monitoring of the instructions and ongoing operation of the EHR tools to ensure proper orientation in each Customer's EHR system
- Capabilities, functionality, and set-up (customization) for each individual OncoEMR system vary. AbbVie shall not be responsible for revising the implementation instructions they provide to any Customer in the event that the Customer modifies or changes its software or the configuration of its EHR system after such time as the implementation instructions have been initially provided by AbbVie
- While EHRs may assist providers in identifying appropriate patients for consideration of assessment and treatment, the decision and action should ultimately be independently decided by a provider in consultation with the patient after a review of the patient's records to determine eligibility. AbbVie shall have no liability thereto
- The instructions have not been designed to and are not tools and/or solutions for meeting Meaningful Use, Advancing Care Information, Promoting Interoperability, and/or any other quality/accreditation requirement
- All products are trademarks of their respective holders, all rights reserved. Reference to these products is not intended to imply affiliation with or sponsorship of AbbVie and/or their affiliates

Please see full Important Safety Information, including **BOXED WARNING**, on pages 6 and 7. Please see full **Prescribing Information**.



# Instructions: OncoEMR

1. Click the User Name in the top right corner and select Customize. A new window will show all customization options
2. Select Regimen List to access all regimens and protocols. Search for existing order sets specific to "BPDCN" by entering the regimen name and/or keywords
3. Set the radio buttons to optimize the search process (My Practice, Me...)
4. If a regimen is available for optimization, select the regimen to start applying the desired changes
5. Edit the Regimen Name. Consider **"DECNUPAZ (pivekimab sunirine-pvzy)"** for the Regimen Name. Set the version number as desired
6. Update the Description and Indication fields
7. Click Add Premed and add the DECNUPAZ Premedications  
Premedication<sup>1</sup>

Administer the premedications in Table 1 the day prior to and the day of the infusion of DECNUPAZ to reduce the risk of infusion-related reactions

**Table 1. Recommended Premedications Prior to Each DECNUPAZ Infusion<sup>1</sup>**

Administration Time Prior to DECNUPAZ Infusion	Premedication	Route of Administration	Dose (or equivalent)
Day before DECNUPAZ infusion	Corticosteroid	Oral or intravenous	Dexamethasone 8 mg twice daily
30 to 60 minutes prior to infusion	Corticosteroid	Intravenous	Dexamethasone 8 mg
	Antihistamine	Intravenous	Diphenhydramine 25 mg to 50 mg
	Antipyretic	Oral	Acetaminophen 325 mg to 650 mg

Please see full Important Safety Information, including **BOXED WARNING**, on pages 6 and 7. Please see full Prescribing Information.

 **Decnupaz**<sup>™</sup>  
pivekimab sunirine-pvzy  
injection for intravenous use 2 mg

# Instructions: OncoEMR (cont'd)

8. In the reference text field, enter *For important information about DECNUPAZ, refer to the PI here: [www.rxabbvie.com/pdf/decnupaz\\_pi.pdf](http://www.rxabbvie.com/pdf/decnupaz_pi.pdf)*  
 Consider additional rows for DECNUPAZ patient education and assistance resources and any other information related to DECNUPAZ

**Table 2. Recommended Dosage Modifications for DECNUPAZ Due to Adverse Reactions<sup>1</sup>**

Adverse Reaction	Severity of Adverse Reaction*	Dose Modification Guidelines
<b>Veno-occlusive disease (VOD)</b>	Any grade	<ul style="list-style-type: none"> <li>Permanently discontinue</li> </ul>
<b>Increased aspartate aminotransferase (AST) or alanine aminotransferase (ALT)</b>	Either AST or ALT is $>2.5 \times$ ULN	<ul style="list-style-type: none"> <li>Delay further dosing until AST or ALT have returned to <math>\leq 2.5 \times</math> ULN</li> </ul>
<b>Increased bilirubin</b>	Total bilirubin $>1.5 \times$ ULN	<ul style="list-style-type: none"> <li>Delay further dosing until total bilirubin has returned to <math>\leq 1.5 \times</math> ULN</li> </ul>
<b>Infusion-related reactions</b>	Grade 2	<ul style="list-style-type: none"> <li>Interrupt infusion and institute appropriate medical management</li> <li>After full resolution of symptoms, resume infusion at 50% of the previous rate and if no further symptoms appear, increase rate as appropriate until infusion is completed</li> </ul>
	Grade 3	<ul style="list-style-type: none"> <li>Stop infusion and institute appropriate medical management</li> <li>After full resolution of symptoms, resume DECNUPAZ infusion at 50% of the previous rate</li> <li>If symptoms recur, permanently discontinue</li> </ul>
	Grade 4	<ul style="list-style-type: none"> <li>Permanently discontinue</li> </ul>
<b>Edema</b>	Grade 1 (5-10% inter-limb discrepancy in volume or circumference, 4 kg weight gain, or 1+ pitting edema [2 mm])	<ul style="list-style-type: none"> <li>Follow weekly weights</li> <li>Consider administering diuretic therapy</li> </ul>
	Grade 2 (10-30% inter-limb discrepancy in volume or circumference, $>4$ kg weight gain, or 2+ pitting edema [4 mm])	<ul style="list-style-type: none"> <li>Administer diuretic therapy</li> <li>Manage hypoalbuminemia as needed</li> <li>Delay further dosing until edema has returned to Grade 0-1 or baseline</li> <li>If delayed more than 2 weeks, consider dose reduction before resuming</li> </ul>
	Grade 3 ( $>30\%$ inter-limb discrepancy in volume, or 3+/4+ pitting edema [ $>6$ mm])	<ul style="list-style-type: none"> <li>Consider combination diuretic therapy</li> <li>Manage hypoalbuminemia as needed</li> <li>Delay further dosing until edema has returned to Grade 0-1 or baseline</li> <li>Consider resuming infusion at 0.015 mg/kg intravenously once every 3 weeks</li> </ul>
	Grade 4 (life-threatening)	<ul style="list-style-type: none"> <li>Permanently discontinue</li> </ul>
<b>Other non-hematologic adverse reactions</b>	Grade 3	<ul style="list-style-type: none"> <li>Delay further dosing until resolved to <math>\leq</math> Grade 2 or baseline</li> </ul>
	Grade 4	<ul style="list-style-type: none"> <li>Permanently discontinue</li> </ul>

\*National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE) version 4.03; Grade 1 is mild, Grade 2 is moderate, Grade 3 is severe, and Grade 4 is life-threatening.<sup>1</sup>

ULN, upper limit of normal.

**Please see full Important Safety Information, including BOXED WARNING, on pages 6 and 7. Please see full Prescribing Information.**



# Instructions: OncoEMR (cont'd)

## **DECNUPAZ Warnings (including Boxed Warning), Precautions, and Adverse Reactions**

- See section 5 of the DECNUAZ PI for Warnings and Precautions (Hepatotoxicity including Veno-occlusive Disease [VOD], Infusion-Related Reactions, Edema, Sulfite Allergic Reactions, and Embryo-Fetal Toxicity): [www.rxabbvie.com/pdf/decnupaz\\_pi.pdf](http://www.rxabbvie.com/pdf/decnupaz_pi.pdf)
- See section 6 of the DECNUAZ PI for Adverse Reactions (Clinical Trials Experience): [www.rxabbvie.com/pdf/decnupaz\\_pi.pdf](http://www.rxabbvie.com/pdf/decnupaz_pi.pdf)

9. Click Add Drug to add DECNUAZ to the treatment regimen:

- a) Day 1: DECNUAZ 0.045 mg/kg administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity<sup>1</sup>

10. Complete the Component Calendar:

- a) Cycles and Days settings. Set the Cycle Lengths and Count (cLEn1: 21 days, cNum1: until disease progression or unacceptable toxicity)

11. Click Save

12. Validate the new regimen, and after satisfactory testing has been completed, release to production

# Indication and Important Safety Information

## INDICATION

DECNUPAZ™ (pivekimab sunirine-pvzy) is indicated for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).

## IMPORTANT SAFETY INFORMATION

### BOXED WARNING: HEPATOTOXICITY, INCLUDING HEPATIC VENO-OCCLUSIVE DISEASE (VOD) (ALSO KNOWN AS SINUSOIDAL OBSTRUCTION SYNDROME)

- DECNUPAZ can cause hepatotoxicity, including severe or fatal hepatic VOD (also known as sinusoidal obstruction syndrome).
- Closely monitor patients for signs and symptoms of VOD, including elevations in liver tests, hepatomegaly (which may be painful), 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 elevation. Permanently discontinue DECNUPAZ for patients who experience VOD.

## WARNINGS AND PRECAUTIONS

### Hepatotoxicity, Including Hepatic VOD

- DECNUPAZ can cause hepatotoxicity, including VOD, a severe form of hepatotoxicity. In CADENZA, VOD occurred in 6% (7/116) of adult patients during treatment or following a subsequent hematopoietic stem cell transplantation (HSCT). Of the 7 total patients that developed VOD, 3 patients had treatment-naïve BPDCN and 4 patients had relapsed/refractory BPDCN. Among all 116 patients treated with DECNUPAZ at 0.045 mg/kg, VOD occurred in 2/116 (2%) during treatment, with onset up to 30 days after the last dose. Among 19 patients with BPDCN who proceeded to HSCT, VOD occurred in 5/19 patients (26%), including 2 fatal cases. The median time from subsequent HSCT to onset of VOD was 11 days (range: 7-25 days).
- After receiving DECNUPAZ, patients should be closely monitored for signs and symptoms of VOD, including elevations in ALT, AST, and total bilirubin; hepatomegaly (which may be painful); rapid weight gain; and ascites. Monitor liver tests, including ALT, AST, and total bilirubin, prior to each dose of DECNUPAZ. Based on elevations of liver tests, delay DECNUPAZ. In patients who experience VOD, discontinue DECNUPAZ and treat according to standard medical practice.

### Infusion-Related Reactions

- DECNUPAZ can cause serious, life-threatening infusion-related reactions (IRR); signs and symptoms of IRR include dyspnea, flushing, fever, chills, nausea, chest discomfort, hypotension, and vomiting. In CADENZA, IRR occurred in 26% (30/116) of patients during treatment with DECNUPAZ at 0.045 mg/kg once every 3 weeks, including Grade 1 in 4.3% (5/116), Grade 2 in 16% (19/116), and Grade 3 in 5% (6/116) of patients. IRR occurred in Cycle 1 in 25% (29/116) of patients with decreasing frequency in subsequent cycles. IRR led to discontinuation in 1 patient.
- Premedicate with a corticosteroid the day before infusion, and premedicate with a corticosteroid, antihistamine, and antipyretic prior to dosing. Premedication the day before infusion and prior to dosing led to reduced frequency and severity of IRR.
- Monitor patients closely for potential IRR during the infusion and for at least 4 hours, or longer as clinically indicated, after the first infusion and for at least 1 hour after subsequent infusions.
- Interrupt infusion of DECNUPAZ and institute appropriate medical management if an infusion-related reaction occurs. Depending on the severity of the infusion-related reaction, reduce infusion rate or permanently discontinue.

Please see additional Important Safety Information on page 7. Please see full [Prescribing Information](#), including **BOXED WARNING**.

 **Decnupaz™**  
pivekimab sunirine-pvzy  
injection for intravenous use 2 mg

# Important Safety Information (cont'd)

## Edema

- DECNUPAZ can cause edema and fluid retention, including serious events. In CADENZA, Grade 3-4 edema occurred in 16% (18/116) of patients treated with DECNUPAZ, including Grade 3-4 generalized edema in 2.6% (3/116) of patients.
- Monitor patients for new or worsening edema. For Grade 2 or 3 edema, delay further dosing of DECNUPAZ until edema has returned to Grades 0-1 or baseline. For Grade 3 edema or Grade 2 edema with dose delay for more than 2 weeks, consider resuming at a lower dose. For Grade 4 edema, permanently discontinue. Institute appropriate medical management for edema.

## Sulfite Allergic Reactions

- DECNUPAZ contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. The overall prevalence of sulfite sensitivity in the general population is unknown and probably low. Sulfite sensitivity is seen more frequently in asthmatic than in non-asthmatic people.

## Embryo-Fetal Toxicity

- Based on its mechanism of action, DECNUPAZ can cause embryo-fetal harm when administered to a pregnant woman because it contains a genotoxic compound (FGN849) and affects actively dividing cells.
- Advise patients of the potential risk to the fetus. 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.

## ADVERSE REACTIONS

- Serious adverse reactions occurred in 55% of patients treated with DECNUPAZ. The most common ( $\geq 2\%$ ) serious adverse reactions were febrile neutropenia, pneumonia, edema, sepsis, hemorrhage, thrombosis, infusion-related reactions, viral infection, pneumonitis, infections without pathogens identified, pyrexia, and musculoskeletal pain. Fatal adverse reactions occurred in 4.3% of patients who received DECNUPAZ, including cardiac arrest (0.9%), clostridium difficile infection (0.9%), failure to thrive (0.9%), depressed level of consciousness (0.9%), and respiratory failure (0.9%).
- The most common adverse reactions ( $\geq 20\%$ ) were edema, fatigue, musculoskeletal pain, hemorrhage, infusion-related reactions, nausea, and diarrhea.
- The most common Grade 3 or 4 laboratory abnormalities ( $\geq 10\%$ ) were decreased neutrophils, decreased platelets, decreased lymphocyte count, decreased white blood cell count, decreased hemoglobin, and increased glucose.

## DRUG INTERACTIONS

- FGN849 is a substrate of CYP3A. Closely monitor patients for adverse reactions with DECNUPAZ when used concomitantly with strong and moderate CYP3A inhibitors.

## USE IN SPECIAL POPULATIONS

- **Lactation:** Advise women not to breastfeed during treatment with DECNUPAZ and for 1 month after the last dose.
- **Renal Impairment:** Avoid use of DECNUPAZ in patients with moderate to severe renal impairment (CL<sub>cr</sub> <60 mL/min, estimated by Cockcroft-Gault) or patients with end-stage renal disease.
- **Hepatic Impairment:** Avoid use of DECNUPAZ in patients with moderate to severe hepatic impairment (total bilirubin >1.5 x ULN with any AST).

**Please see additional Important Safety Information, including BOXED WARNING, on page 6. Please see full Prescribing Information.**

Reference: 1. DECNUPAZ [package insert]. North Chicago, IL: AbbVie Inc.

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 **Decnupaz™**  
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injection for intravenous use 2 mg