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

Veradigm®

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

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USES AND LIMITATIONS

These instructions are specifically related to including DECNUPAZ™ (pivekimab sunirine-pvzy) for its approved indication in the Veradigm 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 Veradigm 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
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Instructions: Veradigm

ACCESSING VERADIGM EHR REQUIRES ADMINISTRATIVE PRIVILEGES. CONSIDER CREATING OR MODIFYING AN ENTERPRISE TEMPLATE.

1. Select TW Admin and click on the CareGuide Admin tab
2. Search for CareGuides for patients with Blastic Plasmacytoid Dendritic Cell Neoplasm (BPDCN) to optimize
3. The optimized order set can be saved under a different name. Keep the CareGuide in draft status until satisfactory testing has been completed
4. Enter **DECNUPAZ™ (pivekimab sunirine-pvzy)** for the description
5. Click the Order Set section (below Monograph) to make changes to the order set content (Medications, MedAdmins, Orders, Instructions, Precautions and Follow-ups, and Referrals)
6. In the Order Set section of the CareGuide, select the Rx and MedAdmins tab and set up the treatment regimen
7. Click Add New Group and add a new node
   a. Enter DECNUPAZ (or name as desired) for the node name
   b. 3 weeks (21 days) per cycle
   c. **DECNUPAZ:** Complete the DECNUPAZ medication details: 0.045 mg/kg administered once every 3 weeks (21-day cycle) as an intravenous infusion until disease progression or unacceptable toxicity[1]
   d. Right-click the Group Name and enter *See URL for additional DECNUPAZ dosing and administration information:* www.rxabbvie.com/pdf/decnupaz_pi.pdf
8. In the Medications tab, click Add New Group and add a new node
9. Enter Premedications before DECNUPAZ as the New Group Name
   a. Premedication[1]

      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[1]

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.

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Instructions: Veradigm (cont'd)

10. In the Precautions tab, click Add New Group and add a new node

11. Enter Dosage Modifications for Adverse Reactions as the New Group Name

a. Right-click the Group Name and enter Recommended Dosage Modifications for Adverse Reactions

Table 2. Recommended Dosage Modifications for DECNUPAZ Due to Adverse Reactions[1]

Adverse Reaction	Severity of Adverse Reaction*	Dose Modification Guidelines
Veno-occlusive disease (VOD)	Any Grade	• Permanently discontinue
Increased aspartate aminotransferase (AST) or alanine aminotransferase (ALT)	Either AST or ALT is >2.5 × ULN	• Delay further dosing until AST or ALT have returned to ≤2.5 × ULN
Increased bilirubin	Total bilirubin >1.5 × ULN	• Delay further dosing until total bilirubin has returned to ≤1.5 × ULN
Infusion-related reactions	Grade 2	• Interrupt infusion and institute appropriate medical management • 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
	Grade 3	• Stop infusion and institute appropriate medical management • After full resolution of symptoms, resume the infusion at 50% of the previous rate • If symptoms recur, permanently discontinue
	Grade 4	• Permanently discontinue
Edema	Grade 1 (5-10% inter-limb discrepancy in volume or circumference, 4 kg weight gain, or 1+ pitting edema [2 mm])	• Follow weekly weights • Consider administering diuretic therapy
	Grade 2 (10-30% inter-limb discrepancy in volume or circumference, >4 kg weight gain, or 2+ pitting edema [4 mm])	• Administer diuretic therapy • Manage hypoalbuminemia as needed • Delay further dosing until edema has returned to Grade 0-1 or baseline • If delayed more than 2 weeks, consider dose reduction before resuming
	Grade 3 (>30% inter-limb discrepancy in volume, or 3+/4+ pitting edema [>6 mm])	• Consider combination diuretic therapy • Manage hypoalbuminemia as needed • Delay further dosing until edema has returned to Grade 0-1 or baseline • Consider resuming infusion at 0.015 mg/kg intravenously once every 3 weeks
	Grade 4 (life-threatening)	• Permanently discontinue
Other non-hematologic adverse reactions	Grade 3	• Delay further dosing until resolved to ≤Grade 2 or baseline
	Grade 4	• Permanently discontinue

*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.[1]

ULN, upper limit of normal.

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Instructions: Veradigm (cont'd)

12. In the Precautions tab, click Add New Group and add a new node

13. Enter Warnings (including Boxed Warning), Precautions, and Adverse Reactions as the New Group Name
    a. Right-click the Group Name and enter: See section 5 of the DECNUPAZ PI for Warnings and Precautions (Hepatotoxicity Including Veno-occlusive Disease [VOD], Infusion-Related Reactions, Edema, Sulfite Allergic Reactions, Embryo-Fetal Toxicity) and see section 6 of the DECNUPAZ PI for Adverse Reactions (Clinical Trials Experience): www.rxabbvie.com/pdf/decnupaz_pi.pdf

14. In the Instructions tab, click Add New Group and add a new node

15. Enter the Display Name **DECNUPAZ™ (pivekimab sunirine-pvzy)**

16. Save the newly updated CareGuide and save as a draft to allow testing

17. Mark as reviewed and release after satisfactory testing has been completed

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.

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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 (≥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 (≥20%) were edema, fatigue, musculoskeletal pain, hemorrhage, infusion-related reactions, nausea, and diarrhea.
- The most common Grade 3 or 4 laboratory abnormalities (≥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 (CLcr <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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