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

SAMPLE LETTER OF APPEAL

This is intended as a TEMPLATE Letter of Appeal

Decnupaz™ Support Services

<Date>

<Contact name of Appeals Department Pharmacy Director or other payer representative> <Contact title>

<Name of health insurance company>

<Address>

Dear <Contact name>,

I am writing on behalf of my patient, <Patient name>, to request an appeal of the claim denial for the administration of DECNUPAZ™ (pivekimab sunirine-pvzy) for the treatment of adult patients with blastic plasmacytoid dendritic cell neoplasm (BPDCN).[1] <Payer name> has indicated the reason for denial, as outlined in the Explanation of Benefits, was <Reasons for denial from Explanation of Benefits>.

As you may be aware, DECNUPAZ was approved by the US Food and Drug Administration on May 27, 2026. My patient, <Patient name>, has received a diagnosis of <patient diagnosis> (see medical history below and attached).

<Patient name> is <a/an age>-year-old diagnosed on <Month Day, Year>. <Patient name> has been in my care since <Month Day, Year>, and in my clinical judgment, requires treatment with DECNUPAZ™. <Discuss clinical history and treatment plan, including information such as patient's condition, treatment history, recommended treatment course, rationale for using product, and potential impact if they don't receive this therapy.>

Based on the information provided within this letter, DECNUPAZ is indicated and medically necessary for the treatment of this patient. Therefore, I respectfully request that <Payer name> cover DECNUPAZ when prescribed for <Patient name>.

Please refer to the enclosed supporting documents for further details, and please don't hesitate to contact me at <Telephone number> if you have any further questions regarding this request.

Thank you for your prompt attention to this matter.

<Doctor's name>, <MD>

cc: <Patient name>

<Optional enclosures: FDA Approval Letter, DECNUPAZ Prescribing Information, and medical records.>

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.**

Please see Important Safety Information, including BOXED WARNING on Hepatotoxicity including Hepatic Veno-Occlusive Disease (VOD) (also known as Sinusoidal Obstruction Syndrome). Please see additional Important Safety Information on the following page.

Please see accompanying full Prescribing Information, or visit https://www.rxabbvie.com/pdf/decnupaz_pi.pdf

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

Decnupaz™ Support Services

IMPORTANT SAFETY INFORMATION (cont'd)

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.

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 accompanying full Prescribing Information, including BOXED WARNING on Hepatotoxicity including Hepatic Veno-Occlusive Disease (VOD), or visit https://www.rxabbvie.com/pdf/decnupaz_pi.pdf

Reference: 1. DECNUPAZ [package insert]. AbbVie, Inc., 2026.

abbvie

US-PVEK-250034 May 2026 032614