Sample letter of medical necessity

You can use this sample letter of medical necessity to provide the reasons that, in your clinical judgment, VEOPOZ® (pozelimab-bbfg) is necessary for your patient. The letter should explain why VEOPOZ is being requested and give health plans additional information to understand the request for approval of VEOPOZ.

Please note that providing such a letter does not guarantee the health plan will offer reimbursement for VEOPOZ, and this information is not intended to substitute for or influence the physician's independent medical judgment. The sample letter is provided for your guidance only.

Some key reminders:

- You may consider including a letter of medical necessity, like this one, with your prior authorization request to emphasize the medical necessity for VEOPOZ, or in addition to your appeal letter, as needed
- Letters of medical necessity should be signed by the physician only

Some health plans require a letter of medical necessity along with supporting documentation,* such as:

- Patient's medical records
- Peer-reviewed literature
- Supporting clinical studies
- Prescribing Information for VEOPOZ
- Clinical notes and laboratory results

ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*.
*To avoid any delays in reimbursement, it is recommended to provide as much documentation as possible.

For assistance, call us at 1-855-5VEOPOZ (1-855-583-6769) Monday–Friday, 9 AM–9 PM Eastern time.

VEOPOZ is indicated for the treatment of adult and pediatric patients 1 year of age and older with CD55-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS MENINGOCOCCAL INFECTIONS

• Life-threatening and fatal meningococcal infections have occurred in patients treated with complement inhibitors. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early.

• Complete or update meningococcal vaccination (for serogroups A, C, W, and Y, and serogroup B) at least 2 weeks prior to administering the first dose of VEOPOZ, unless the risks of delaying therapy outweigh the risk of developing a meningococcal infection. Follow the most current Advisory Committee on Immunization Practices (ACIP) recommendations for meningococcal vaccination in patients receiving a complement inhibitor.

• Patients receiving VEOPOZ are at increased risk for invasive disease caused by *Neisseria meningitidis*, even if they develop antibodies following vaccination. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected.

Please see Important Safety Information throughout and click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

IMPORTANT SAFETY INFORMATION (cont'd)

Contraindications

- Patients with unresolved *Neisseria meningitidis* infection

Warnings and Precautions

Serious Meningococcal Infections: Life-threatening and fatal meningococcal infections have occurred in both vaccinated and unvaccinated patients treated with complement inhibitors. The use of VEOPOZ increases a patient's susceptibility to serious and life-threatening meningococcal infections (septicemia and/or meningitis) caused by any serogroup, including nongroupable strains.

Complete or update meningococcal vaccination (for serogroups A, C, W, and Y [MenACWY] and serogroup B [MenB]) at least 2 weeks prior to administering the first dose of VEOPOZ, according to the most current ACIP recommendations for patients receiving a complement inhibitor. Revaccinate patients in accordance with ACIP recommendations considering the duration of VEOPOZ therapy.

If urgent VEOPOZ therapy is indicated in a patient who is not up-to-date with both MenACWY and MenB vaccines according to ACIP recommendations, administer meningococcal vaccine(s) as soon as possible and provide the patient with antibacterial drug prophylaxis. The efficacy, duration, and drug regimens for antibacterial drug prophylaxis have not been studied in patients receiving complement inhibitors.

Because of inhibition of complement activity by VEOPOZ, as well as risk of infection caused by nongroupable strains of *Neisseria meningitidis*, vaccination does not eliminate the risk of meningococcal infections, despite development of antibodies following vaccination.

Closely monitor patients for early signs and symptoms of meningococcal infection and evaluate patients immediately if infection is suspected. Inform patients and caregivers of these signs and symptoms, and instruct patients to seek immediate medical care if these signs and symptoms occur. Meningococcal infection may become rapidly life-threatening or fatal if not recognized and treated early. Interrupt treatment with VEOPOZ in patients who are undergoing treatment for serious meningococcal infection until the infection is resolved.

Other Bacterial Infections: VEOPOZ blocks terminal complement activation; therefore, patients may have increased susceptibility to encapsulated bacterial infections, especially infections with *Neisseria meningitidis*, but also *Streptococcus pneumoniae* and *Haemophilus influenzae,* and to a lesser extent, *Neisseria gonorrhoeae*. Patients treated with VEOPOZ may be at increased risk of developing serious infections due to *Streptococcus pneumoniae* and *Haemophilus influenzae* type b (Hib). Vaccinate for the prevention of *Streptococcus pneumoniae* and Hib infections according to ACIP guidelines. Patients receiving VEOPOZ are at increased risk for infections due to these organisms, even if they develop antibodies following vaccination. Interrupt treatment with VEOPOZ in patients who are undergoing treatment for a serious encapsulated bacterial infection until the infection is resolved. Counsel patients about gonorrhea prevention and advise regular testing for patients at risk.

Systemic Hypersensitivity Reactions: Hypersensitivity reactions, including anaphylaxis, have been reported with administration of complement inhibitors. Interrupt VEOPOZ and institute appropriate supportive measures if signs of cardiovascular instability or respiratory compromise occur.

Please see Important Safety Information throughout and click here for full Prescribing Information, including Boxed WARNING, and Medication Guide.

Immune Complex Formation: Immune complex formation has been reported during the transition of therapy between complement inhibitors, resulting in transient decrease in drug concentrations as well as symptoms suggestive of hypersensitivity reactions. However, this has not been studied in patients with CD55-deficient protein-losing enteropathy (PLE) switching from other complement inhibitors to VEOPOZ. The potential for immune complex formation should be considered if switching complement inhibitors.

Drug Interactions

Intravenous Immunoglobulin (IVIg): Avoid concomitant use of IVIg with VEOPOZ. If concomitant use cannot be avoided, monitor patients for worsening of clinical signs and symptoms of CD55-deficient PLE.

Use in Specific Populations

Pregnancy: Although there are no data on VEOPOZ use in pregnant women to inform a drug-associated risk of major birth defects, miscarriage, or adverse maternal or fetal outcomes, monoclonal antibodies can be actively transported across the placenta.

Lactation: There are no data on the presence of VEOPOZ in human milk or animal milk, the effects on the breastfed infant, or the effects on milk production. Endogenous maternal IgG and monoclonal antibodies are transferred into human milk. The development and health benefits of breastfeeding should be considered along with the mother's clinical need for VEOPOZ and any potential adverse effects on the breastfed infant from VEOPOZ or from the underlying maternal condition.

Pediatric: The safety and effectiveness of VEOPOZ have not been established in pediatric patients less than 1 year of age.

Adverse Reactions

The most common adverse reactions (in two or more patients) are upper respiratory tract infection, fracture, urticaria, and alopecia.

Please see full Prescribing Information, including Boxed WARNING, for VEOPOZ.

REGENERON®

07/2024 US.VEO.24.06.0026

Veopoz® (pozelimab-bbfg) Injection

Sample letter of medical necessity

[Use physician's letterhead]

[Date]

[Health Plan Contact Name]
[Title]
[Health Plan Organization Name]
[Address]
[City, State ZIP]

Re: [Subject line]

Patient: [Patient Name]
Date of Birth: [Patient DOB]
Insurance Policy ID Number: [Policy ID Number]
Group Number: [Group Number]
Claim Number: [Claim Number]

Dear [Health Plan Contact Name],

I am writing on behalf of my patient, [Patient full name], to document the medical necessity of VEOPOZ® (pozelimab-bbfg). Included below is additional information about the patient's medical history and diagnosis of [diagnosis] (ICD-10-CM code: [code]), as well as a statement summarizing my treatment rationale.

VEOPOZ is a human, monoclonal immunoglobulin G4^{P} (IgG4^{P}) antibody directed against the terminal complement protein C5 that inhibits terminal complement activation by blocking cleavage of C5 into C5a (anaphylatoxin) and C5b, thereby blocking the formation of the membrane-attack complex (C5b-C9, a structure-mediating cell lysis).[1] VEOPOZ is indicated for the treatment of adults and pediatric patients 1 year of age and older with *CD55*-deficient protein-losing enteropathy (PLE), also known as CHAPLE disease.[1]

Overview of CHAPLE disease

CD55-deficient protein-losing enteropathy, also known as CHAPLE disease, is a potentially life-threatening, autosomal recessive disease caused by rare, loss-of-function mutations of the *CD55* gene.[2] Active *CD55*-deficient PLE is often defined as hypoalbuminemia (serum albumin concentration of ≤3.2 g/dL) and may present with symptoms such as abdominal pain, diarrhea, and peripheral or facial edema.[1]

CHAPLE disease often presents in children before the age of 2 years, although it can present later in life.[2] CHAPLE is an ultra-rare disease that is estimated to occur in less than 1 person in every 1,000,000.[3,4]

Summary of patient's medical history *Note to physician: Modify this section as appropriate based on your clinical judgment of the patient's diagnosis and medical condition.*

The patient's medical history includes [information from clinical diagnosis; information that summarizes the patient's treatment history; response to past therapies; any recent symptoms and conditions, if applicable; opinion of the patient's prognosis with and without treatment with VEOPOZ; and the length of time the patient is anticipated to stay on therapy.]

1. Confirmation of patient CHAPLE clinical diagnosis
    - Age at diagnosis and diagnosing clinician [indicate patient report/documentation attached]
    - [Genetic testing results confirming biallelic *CD55* loss-of-function mutation]
2. Information regarding the patient's current signs and symptoms presentation
3. Information regarding recent hospitalizations

[Product Information: Placeholder to include any relevant information copied from Prescribing Information.]

In summary, VEOPOZ® (pozelimab-bbfg) is medically necessary for this patient's rare medical condition, and [health plan name] should cover this product for my patient without delay. Please contact me at [phone number] if additional information is required to ensure prompt approval of this course of treatment.

Sincerely,

[Physician's name, degree(s), participating provider ID number, and signature]

Enclosures: [Attach VEOPOZ Prescribing Information, including boxed WARNING, and any additional documentation, as appropriate]

References: 1.VEOPOZ® (pozelimab-bbfg) injection full U.S. prescribing information. Regeneron Pharmaceuticals, Inc. **2.** Ozen A, Comrie WA, Ardy RC, et al. CD55 deficiency, early-onset protein-losing enteropathy, and thrombosis. *N Engl J Med.* 2017;377(1):52-61. **3.** Sardella M, Belcher G. Pharmacovigilance of medicines for rare and ultrarare diseases. *Ther Adv Drug Saf.* 2018;9(11):631-638. **4.** Complement hyperactivation-angiopathic thrombosis-protein-losing enteropathy syndrome. Orphanet. Updated July 25, 2023. Accessed June 24, 2024. https://www.orpha.net/en/disease/detail/566175