Part B Prior Authorization Guidelines

CHAPLE Diease

Veopoz (pozelimab-bbfg) J9376

Prior Authorization Request

Medicare Part B Form

*Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	Date Requested _____		
	Requestor _____ Clinic name: _____ Phone / Fax		

MEMBER INFORMATION

*Name:_____ *ID#:_____ *DOB:_____

PRESCRIBER INFORMATION

*Name:_____ ☐MD ☐FNP ☐DO ☐NP ☐PA *Phone:_____

*Address:_____ *Fax:_____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name:_____ Phone:_____

*Address:_____ Fax:_____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐Chart notes attached. **Other important information:**_____

Diagnosis: ICD10: _____ **Description**: _____

☐ Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

☐ **New Start or Initial Request: (Clinical documentation required for all requests)**

- ☐ Diagnosis of CD55-deficient PLE or CD55 deficiency with complement hyperactivation, angiopathic thrombosis, protein-losing enteropathy (i.e., CHAPLE disease); AND
- ☐ Submission of medical records (e.g., chart notes, laboratory values) confirming a biallelic loss-of-function mutation in the CD55 gene; AND
- ☐ Laboratory results, signs, and/or symptoms attributed to CHAPLE disease (e.g., hypoalbuminemia, peripheral or facial edema, abdominal pain, diarrhea, etc.); AND
- ☐ Patient is not receiving Veopoz in combination with Soliris (eculizumab) or Ultomiris (ravulizumab); AND
- ☐ Dosing is in accordance with the United States Food and Drug Administration approved labeling; AND
- ☐ Prescribed by a hematologist or other specialist with expertise in the diagnosis of CHAPLE disease;AND
- ☐ Initial authorization will be for no more than 6 months

If not, please provide **clinical rationale** for formulary exception: _____

_____

☐ **Continuation Requests: (Clinical documentation required for all requests)**

- ☐ Documentation demonstrating a positive clinical response from baseline (e.g., normalization of serum albumin, reduction of peripheral or facial edema, reduction in abdominal pain or diarrhea); AND
- ☐ Patient is not receiving Veopoz in combination with Soliris (eculizumab) or Ultomiris (ravulizumab);
- ☐ Patient had an adequate response or significant improvement while on this medication.
  If not, please provide clinical rationale for continuing this medication: _____
  _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____Date:_____ /____ /____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. **THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT.** PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

Prior Authorization Group – CHAPLE Diease PA

Drug Name(s):
VEOPOZ **POZELIMAB-BBFG**

Criteria for approval of Prior Authorization Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.

- If the member meets all these criteria, they may be approved by the Plan for the requested drug.
- Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:
N/A

Prescriber Restrictions:
Hematologist or other Specialist with expertise in the diagnosis of CHAPLE Disease

Coverage Duration:
Initial approval will be for 6 months. Continuation may be approved for up to 12 months.

FDA Indications:
Veopoz

- Complement hyperactivation, angiopathic thrombosis, protein losing enteropathy syndrome

Off-Label Uses:
N/A

Age Restrictions:
1 year or older

Other Clinical Considerations:
Black Box Warning: (IV; Subcutaneous solution)

- 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 pozelimab-bbfg, 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 pozelimab-bbfg are at increased risk for invasive disease caused by N. meningitidis, even if they develop antibodies following vaccination. Monitor patients for early signs of meningococcal infections and evaluate immediately if infection is suspected

Resources:
https://www.micromedexsolutions.com/micromedex2/librarian/CS/ACD4E3/ND_PR/evidencexpert/ND_P/evidencexpert/DUPLICATIONSHIELDSYNC/AFE033/ND_PG/evidencexpert/ND_B/evidencexpert/ND_AppProduct/evidencexpert/ND_T/evidencexpert/PFActionId/evidencexpert.DoIntegratedSearch?SearchTerm=veopoz&UserSearchTerm=veopoz&SearchFilter=filterNone&navitem=searchGlobal#