

# AvMed

## PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST\*

**Directions:** The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

**Drug Requested:** Voydeya™ (danicopan)

**MEMBER & PRESCRIBER INFORMATION:** Authorization may be delayed if incomplete.

Member Name: \_\_\_\_\_

Member Sentara #: \_\_\_\_\_ Date of Birth: \_\_\_\_\_

Prescriber Name: \_\_\_\_\_

Prescriber Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Office Contact Name: \_\_\_\_\_

Phone Number: \_\_\_\_\_ Fax Number: \_\_\_\_\_

NPI #: \_\_\_\_\_

**DRUG INFORMATION:** Authorization may be delayed if incomplete.

Drug Name/Form/Strength: \_\_\_\_\_

Dosing Schedule: \_\_\_\_\_ Length of Therapy: \_\_\_\_\_

Diagnosis: \_\_\_\_\_ ICD Code, if applicable: \_\_\_\_\_

Weight (if applicable): \_\_\_\_\_ Date weight obtained: \_\_\_\_\_

**Recommended Dosage:** 150 mg orally three times daily

- Dose adjustment: May increase dose up to 200 mg 3 times a day if Hb level has not increased by >2 g/dL after 4 weeks of therapy, if a transfusion is required during the previous 4 weeks, or to achieve an appropriate Hb response based on clinical judgement.

**Quantity Limit:** 180 tablets per 30 days

**CLINICAL CRITERIA:** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

**Initial Authorization:** 6 months

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- Medication must be prescribed by or in consultation with a hematologist or nephrologist
- Prescriber must be enrolled in the Voydeya™ Risk Evaluation and Mitigation Strategy (REMS) program
- Member must be 18 years of age or older
- Member must have a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) confirmed by detection of PNH clones of at least 10% by flow cytometry testing (**must submit labs**)
- Flow cytometry pathology report must demonstrate at least two (2) different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within two (2) different cell lines from granulocytes, monocytes, erythrocytes (**must submit labs**)
- Member has been receiving a stable dose of eculizumab (Soliris®) or ravulizumab (Ultomiris®) for at least 6 months
  - Member has laboratory evidence of clinically significant extravascular hemolysis (while receiving Soliris or Ultomiris) as evidenced by **ONE** of the following laboratory findings (**must submit chart notes and labs**):
    - Member has anemia with a hemoglobin less than or equal to 9.5 g/dL
    - Member has an absolute reticulocyte count of greater than or equal to  $120 \times 10^9/L$
    - Member is transfusion dependent (defined by having a transfusion within the last 12 months) and has symptomatic anemia
    - Member has high lactate dehydrogenase (LDH) level (defined as  $\geq 1.5$  times the upper limit of the normal range with clinical symptoms)
    - Presence of a thrombotic event (e.g., DVT, PE)
    - Presence of organ damage secondary to chronic hemolysis (i.e., renal insufficiency, pulmonary insufficiency, or hypertension)
    - Member is pregnant and potential benefit outweighs potential fetal risk
- Member does **NOT** have evidence of an active infection caused by encapsulated bacteria (e.g., *Streptococcus pneumoniae*, *Neisseria meningitidis*, or *Haemophilus influenzae*)
- Member must be vaccinated against encapsulated bacteria (*Streptococcus pneumoniae*, *Neisseria meningitidis*, and *Haemophilus influenzae type B*) **at least two weeks prior** to initiation of Voydeya™ therapy and revaccinated according to current medical guidelines for vaccine use
- Requested medication will **NOT** be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkerv™, Epysqli™, PiaSky®, Empaveli® or Fabhalta®)

**Reauthorization: 12 months.** Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

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- Member has experienced positive disease response indicated by at least **ONE** of the following (**check all that apply; results must be submitted to document improvement**):
  - Stabilization/increase in hemoglobin level
  - Decrease in packed RBC transfusion requirement
  - Decrease in absolute reticulocyte count
  - Decrease in serum LDH level
  - Reduction in thromboembolic events
- Member continues to receive treatment in combination with eculizumab (Soliris<sup>®</sup>) or ravulizumab (Ultomiris<sup>®</sup>)
- Provider attests to an absence of unacceptable toxicity from the drug (e.g., serious meningococcal infections [septicemia and/or meningitis])
- Member does **NOT** have evidence of an active infection caused by encapsulated bacteria (e.g., *Streptococcus pneumoniae*, *Neisseria meningitidis*, or *Haemophilus influenzae type B*)
- Requested medication will **NOT** be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkempv<sup>™</sup>, Epysqli<sup>™</sup>, PiaSky<sup>®</sup>, Empaveli<sup>®</sup>, or Fabhalta<sup>®</sup>)

**Medication being provided by Specialty Pharmacy – Proprium Rx**

***\*\*Use of samples to initiate therapy does not meet step edit/ preauthorization criteria.\*\****  
***\*Previous therapies will be verified through pharmacy paid claims or submitted chart notes.\****