SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-800-750-9692**. 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 x 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 ≥ 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., Bkemv™, 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®) or ravulizumab (Ultomiris®)
- ❑ 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., Bkemv™, Epysqli™, PiaSky®, Empaveli®, or Fabhalta®)

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.****

***Approved by Pharmacy and Therapeutics Committee: 7/25/2024**
REVISED/UPDATED/REFORMATTED: ~~8/21/2024;~~ **10/15/2024**