SENTARA HEALTH PLANS

MEDICAL 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 1-844-668-1550**. No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If information provided is not complete, correct, or legible, authorization can be delayed**.

For Medicare Members: Medicare Coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: https://www.cms.gov/medicare-coverage-database/overview-and-quick-search.aspx. Additional indications may be covered at the discretion of the health plan.

Drug Requested: PiaSky® (crovalimab-akkz) **IV/SQ (J1307) (Medical)**
Paroxysmal Nocturnal Hemoglobinuria (PNH)

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:** _____

❑ Standard Review. In checking this box, the timeframe does not jeopardize the life or health of the member or the member's ability to regain maximum function and would not subject the member to severe pain.

Recommended Dosing: Piasky® 340 mg/2 mL solution in single-dose vials for infusion

- **Weight ≥ 40 kg to <100kg:**
  - **Loading Dose:** 1,000 mg IV (100 billable units) on day 1 followed by 340 mg SQ on days 2, 8, 15, 22
  - **Maintenance Dose:** 680 mg SQ on day 29 and every 4 weeks thereafter
- **Weight ≥ 100 kg:**
  - **Loading Dose:** 1,500 mg IV (150 billable units) on day 1 followed by 340 mg SQ on days 2, 8, 15, 22
  - **Maintenance Dose:** 1020 mg SQ on day 29 and every 4 weeks thereafter

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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

- ❑ Prescribed by or in consultation with a hematologist or nephrologist
- ❑ Prescriber is enrolled in the PiaSky Risk Evaluation and Mitigation Strategy (PIASKY REMS) program
- ❑ Member must be 13 years of age or older
- ❑ Member body weight is at least 40 kg
- ❑ 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 2 different glycosylphosphatidylinositol (GPI) protein deficiencies (e.g., CD55, CD59, etc.) within 2 different cell lines from granulocytes, monocytes, erythrocytes **(must submit labs)**
- ❑ Member must have **ONE** of the following indications for therapy **(must submit chart notes and labs)**:
  - ❑ Member is transfusion dependent as defined by having a transfusion within the last 12 months and **ONE** of the following:
    - ❑ Member's hemoglobin is less than or equal to 7 g/dL
    - ❑ Member has symptoms of anemia, and the hemoglobin is less than or equal to 9 g/dL
  - ❑ 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
  - ❑ 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 PiaSky® therapy and revaccinated according to current medical guidelines for vaccine use
- ❑ Member has **NOT** received a vaccination **at least two weeks prior** to the initiation of therapy with PiaSky® and documented the risks of delaying PiaSky® therapy outweigh the risks of developing an infection
- ❑ Medication will **NOT** be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkemv™, Epysqli™, Soliris®, Ultomiris®, Empaveli®, Fabhalta®, Voydeya™)

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- ❑ PiaSky® will be used as switch therapy **AND** member meets **ALL** the following:
  - ❑ Member is currently receiving treatment with eculizumab or ravulizumab and has shown a beneficial disease response and absence of unacceptable toxicity while on therapy
  - ❑ Provider attests administration of the IV loading dose will occur at the time of the next scheduled C5 inhibitor dose

Reauthorization: 6 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

- ❑ Member continues to meet all initial authorization criteria
- ❑ Provider attests to an absence of unacceptable toxicity from the drug (e.g., serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections)
- ❑ 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)**:
  - ❑ Documentation of a recent (within 3 months) LDH level that shows a reduction from baseline
  - ❑ Documentation that the member has stabilized hemoglobin levels as supported by **ONE** of the following:
    - ❑ Member had a reduction in number of transfusions **OR** units of packed red cells transfused from baseline
    - ❑ Member maintained a hemoglobin concentration above 7 g/dL **OR** maintained a hemoglobin concentration above 9 g/dL if member had a baseline hemoglobin level above 7 g/dL but below 9 g/dL
    - ❑ Member had a reduction in thrombotic events (e.g., DVT, PE)

EXCLUSIONS. Therapy will **NOT** be approved if member has history of any of the following:

- Unresolved meningococcal disease
- Any systemic bacterial or significant infections that have not been treated with appropriate antibiotics

Medication being provided by (check box below that applies):

- ❑ **Location/site of drug administration:** _____

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy**

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For urgent reviews: Practitioner should call Sentara Health Plans Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health Plan's definition of urgent is a lack of treatment that could seriously jeopardize the life or health of the member or the member's ability to regain maximum function.

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: 9/26/2024**
REVISED/UPDATED/REFORMATTED: ~~10/18/2024;~~ 4/24/2025