SENTARA COMMUNITY PLAN
(MEDICAID)

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 1-844-305-2331**. 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**.

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

- ❑ Member has a diagnosis of Paroxysmal Nocturnal Hemoglobinuria (PNH) as confirmed by flow cytometry with at least 2 independent flow cytometry reagents on at least 2 cell lineages (e.g., RBCs and WBCs) demonstrating that the patient's peripheral blood cells are deficient in glycosylphosphatidylinositol (GPI)-linked proteins **(must submit labs)**
- ❑ Member is 13 years of age or older
- ❑ Member body weight is at least 40 kg
- ❑ Must be prescribed by, or in consultation with, a hematologist or other specialist in paroxysmal nocturnal hemoglobinuria
- ❑ Member will **NOT** use requested agent in combination with Soliris (eculizumab), Bkemv (eculizumab-aeeb), Epysqli (eculizumab-aagh), Ultomiris (ravulizumab-cwvz), Fabhalta (iptacopan), or Empaveli (pegcetacoplan)
- ❑ Member must not have unresolved serious *Neisseria meningitidis* infection

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.

- ❑ Member continues to meet all the relevant criteria identified in the initial criteria
- ❑ Member has an absence of unacceptable toxicity from the drug (e.g., serious meningococcal infections (septicemia and/or meningitis), infusion reactions, serious infections)
- ❑ Member is being continuously monitored for a beneficial response to therapy

Medication being provided by: Please check applicable box below.

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

  NPI or DEA # of administering location: _____

  OR

- ❑ **Specialty Pharmacy – PropriumRx**

For urgent reviews: Practitioner should call Sentara Health Pre-Authorization Department if they believe a standard review would subject the member to adverse health consequences. Sentara Health'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;~~ **6/11/2026**