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: PiaSky® (crovalimab-akkz) **SQ (Pharmacy)**
Paroxysmal Nocturnal Hemoglobinuria (PNH)

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

Member Name: _____

Member AvMed #: _____ **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 Dosing: Piasky® 340 mg/2 mL solution in single-dose vials for infusion

- **Weight ≥ 40 kg to <100kg:**
  - **Loading Dose:** 1,000 mg IV 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 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

Quantity Limit: 6 mL (3 vials) per 28 days

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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 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.*