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: Fabhalta® (iptacopan)

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete

Drug Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy**: _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight: _____ **Date:** _____

Recommended Dosage: 200 mg orally twice daily

- Conversion from C5 inhibitors:
  - Conversion from Soliris® (eculizumab): When converting from eculizumab to iptacopan, initiate iptacopan no later than 1 week following the last eculizumab dose.
  - Conversion from Ultomiris® (ravulizumab): When converting from ravulizumab to iptacopan, initiate iptacopan no later than 6 weeks following the last ravulizumab dose.

Quantity Limit: 2 capsules per day

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 Fabhalta® Risk Evaluation and Mitigation Strategy (REMS) program
- ❑ Member must be 18 years of age or older
- ❑ Member must meet **ONE** of the following:
  - ❑ Fabhalta® will be used as switch therapy **AND** member meets **ALL** the following:
    - ❑ Member failed Soliris® or Ultomiris® and must meet renewal criteria
    - ❑ Member does **NOT** have a systemic infection
    - ❑ Member must be vaccinated against encapsulated bacteria (*Streptococcus pneumoniae, Neisseria meningitidis, and Haemophilus influenzae type B)* **at least two weeks prior** to initiation of Fabhalta® therapy and revaccinated according to current medical guidelines for vaccine use
    - ❑ Fabhalta® will **NOT** be used in combination with other complement inhibitor therapies (e.g., Empaveli®, Soliris® or Ultomiris®)

OR

  - ❑ Member is treatment-naive **AND** member meets **ALL** the following:
    - ❑ 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 laboratory evidence of significant hemolysis (i.e. LDH $\geq$ 1.5 x ULN) **AND** has experienced **ONE** of the following additional indications for therapy **(must submit chart notes and labs)**:
      - ❑ Member is transfusion dependent **(defined by having a transfusion within the last 12 months)** and symptomatic anemia
      - ❑ 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 has abdominal pain requiring admission to hospital
  - ❑ Member does **NOT** have a systemic infection
  - ❑ Member must be administered a meningococcal vaccine **at least two weeks prior** to initiation of Fabhalta® therapy and revaccinated according to current medical guidelines for vaccine use
  - ❑ Fabhalta® will **NOT** be used in combination with other complement inhibitor therapies (e.g., Empaveli®, Soliris® or Ultomiris®)

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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.

- ❑ Provider attests to an absence of unacceptable toxicity from the drug (e.g., serious meningococcal infections [septicemia and/or meningitis])
- ❑ 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)**:
  - ❑ Decrease in serum LDH
  - ❑ Stabilization/increase in hemoglobin level
  - ❑ Decrease in packed RBC transfusion requirement
  - ❑ Reduction in thromboembolic events

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 pha rmacy paid claims or submitted chart notes.*