

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: Fabhalta[®] (iptacopan)

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: 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[®], Ultomiris[®] or Voydeya[™])

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 $\geq 1.5 \times$ 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[®], Ultomiris[®] or Voydeya[™])

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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 pharmacy paid claims or submitted chart notes.****