SENTARA HEALTH PLANS

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:

- **Paroxysmal nocturnal hemoglobinuria:** 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.
- **Primary immunoglobulin A nephropathy:** 200 mg orally twice daily
- **Complement 3 glomerulopathy (C3G), to reduce proteinuria:** 200 mg orally twice daily

Quantity Limit: 2 capsules per day **(for ALL indications)**

(Continued on next page)

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.

❑ **Diagnosis: Paroxysmal Nocturnal Hemoglobinuria (PNH)**

Initial Authorization: 6 months

- ❑ 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 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 has 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

(Continued on next page)

- ❑ Fabhalta® will **NOT** be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkemv™, Epysqli™, PiaSky®, Ultomiris®, Soliris® or Empaveli®)

❑ Diagnosis: Paroxysmal Nocturnal Hemoglobinuria (PNH)

Reauthorization: 12 months

- ❑ 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

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.

❑ Primary Immunoglobulin A Nephropathy (IgAN)

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Provider is a nephrologist
- ❑ Member has a diagnosis of biopsy-proven, primary immunoglobulin A nephropathy (IgAN) and is at risk of rapid disease progression
- ❑ Member is currently established on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (angiotensin converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), for at least 90 days **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Members' lab test results taken within the last 30 days must be submitted to document **ALL** the following:
  - ❑ Total urine protein ≥ 1 g/day
  - ❑ Urine protein-to-creatinine ratio is ≥ 1.5 g/g
  - ❑ eGFR ≥ 30 mL/min/1.73 m^2
- ❑ Member will avoid concomitant therapy with major interacting drugs, including **ALL** the following:
  - ❑ Strong CYP2C8 inhibitors (e.g., gemfibrozil)
  - ❑ CYP2C8 inducers (e.g., rifampin)

(Continued on next page)

- ❑ Member must meet **ONE** of the following:
  - ❑ Member has had an unsuccessful 3-month trial of oral generic budesonide EC capsules **(must submit chart notes or lab test results confirming therapy failure)**
  - ❑ Member has an intolerance or hypersensitivity to oral generic budesonide EC capsules, or an FDA labeled contraindication to oral generic budesonide EC capsules that is not expected to occur with the requested agent **(documentation of intolerance or hypersensitivity must be submitted)**
- ❑ Member has had unsuccessful 3-month trials of Vanrafia® or Filspari® **AND** Tarpeyo® **(must submit chart notes or lab test results confirming therapy failure)**
- ❑ Member is **NOT** using concomitant therapy with any of the following: Tarpeyo®, Filspari®, Fabhalta®, Vanrafia® or other complement inhibitor therapies (e.g., Empaveli®, Soliris®, Ultomiris® or Voydeya™)

❑ Diagnosis: Primary Immunoglobulin A Nephropathy (IgAN)

Reauthorization: 12 months

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member must have reduction in proteinuria from baseline after initial approval, and reduction or stabilization in proteinuria after subsequent approvals **(current lab test results must be submitted for documentation)**
- ❑ Member has **NOT** experienced any treatment-restricting adverse effects (e.g., serious and life-threatening infections)

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.

❑ Complement 3 Glomerulopathy (C3G)

Initial Authorization: 6 months

- ❑ Member is 18 years of age or older
- ❑ Provider is a nephrologist
- ❑ Member has a diagnosis of biopsy-proven, Complement 3 Glomerulopathy (C3G) **(must submit biopsy results confirming diagnosis)**
- ❑ Member has **NOT** received a kidney transplant in the past
- ❑ Member is currently established on a stable and maximally tolerated dose of a renin-angiotensin system (RAS) inhibitor (angiotensin converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]), for at least 90 days (verified by chart notes and/or pharmacy paid claims)

(Continued on next page)

- ❑ Member's lab test results taken within the last 30 days must be submitted to document **ALL** the following:
  - ❑ Urine protein-to-creatinine ratio ≥ 1.0 g/g
  - ❑ Estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2
- ❑ Member has had an unsuccessful 90 day trial of at least **ONE** of the following therapies for treatment of C3G **(must submit documentation of therapy failure)**:
  - ❑ Corticosteroids (i.e., prednisone, prednisolone) taken along with mycophenolate or mycophenolic acid (i.e., generic Cellcept, Myfortic)
  - ❑ Rituximab (i.e., Rituxan, Ruxience, Truxima)
- ❑ Member will **NOT** be using Fabhalta® as concomitant therapy with any of the following: Empaveli®, Soliris®, Tavneos®, Ultomiris®, Voydeya™ or other complement inhibitor therapies

❑ Diagnosis: Complement 3 Glomerulopathy (C3G)

Reauthorization: 12 months

- ❑ Member continues to meet all initial authorization criteria
- ❑ Member must have reduction in urine protein-to-creatinine ratio (UPCR) or proteinuria from baseline after initial approval, and reduction or stabilization in UPCR or proteinuria after subsequent approvals **(current lab test results must be submitted for documentation)**
- ❑ Member has **NOT** experienced any treatment-restricting adverse effects (e.g., serious and life-threatening infections)

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.*

***Approved by Pharmacy and Therapeutics Committee**: ~~3/21/2024;7/25/2024;~~ ~~9/26/2024;~~ **5/22/2025**
REVISED/UPDATED/REFORMATTED: ~~4/26/2024; 8/21/2024;~~ ~~10/15/2024;~~ **6/09/2025**