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 ≥ 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.

❑ Diagnosis: 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 **NOT** currently receiving dialysis and has **NOT** undergone a kidney transplant
- ❑ Member is currently established on a stable and maximally tolerated dose of a renin-angiotensin-aldosterone system (RAAS) 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 **OR** urine protein-to-creatinine ratio is ≥ 1.0 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)
- ❑ Member does **NOT** have a systemic infection

(Continued on next page)

- ❑ 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
- ❑ 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™, Voyxact®, 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's lab test results taken within the last 30 days must be submitted to document eGFR ≥ 30 mL/min/1.73 m^2
- ❑ 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.

❑ Diagnosis: 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-aldosterone system (RAAS) 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 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
- ❑ 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 pharmacy paid claims or submitted chart notes.*

***Approved by Pharmacy and Therapeutics Committee**: ~~3/21/2024;7/25/2024;~~ ~~9/26/2024; 5/22/25~~ **1/22/2026**
REVISED/UPDATED/REFORMATTED: ~~4/26/2024; 8/21/2024;~~ ~~10/15/2024; 6/09/2025;~~ **3/6/2026**