

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: _____

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)

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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.

☐ 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 $\geq 1.5 \times$ 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 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

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- Fabhalta® will **NOT** be prescribed concurrently with another FDA approved product prescribed for treatment of PNH (e.g., Bkembv™, 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 m²
- 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

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- ❑ 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 m²
- ❑ 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**)

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- ❑ 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 m²
- ❑ 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.****