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: Filspari (sparsentan)

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:

- Immunoglobulin A Nephropathy (IgAN) – Oral: Initial: 200 mg once daily for 14 days. On day 15, increase to 400 mg once daily (recommended dose), if tolerated.
- Focal Segmental Glomerulosclerosis (FSGS) without Nephrotic Syndrome in adult and pediatric patients 8 years and older:
  - Weight > 50 kg: Initial: 400 mg orally once daily. After 14 days, increase to 800 mg once daily, as tolerated.
  - Weight ≤ 50 kg: Initial: 200 mg orally once daily. After 14 days, increase to 400 mg once daily, as tolerated.

Quantity Limit:

- IgAN – 1 tablet per day (all strengths)
- FSGS – 200 mg (1 tablet per day); 400 mg (2 tablets per day)

(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: 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)**
- ❑ Member's 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
- ❑ Provider attests that member's liver aminotransferases and total bilirubin will be measured prior to starting Filspari® and ALT and AST will be assessed regularly during treatment
- ❑ Provider attests that a pregnancy test in members with child-bearing potential will be completed prior to treatment initiation with Filspari®, and member will use effective contraception prior to and during treatment
- ❑ Due to increased risk for hypotension, syncope, hyperkalemia, and changes in renal function, member will discontinue use of **ALL** ACE inhibitors (such as lisinopril, enalapril, ramipril) and ARBs (such as valsartan, losartan and irbesartan) while using Filspari®
- ❑ Member will avoid concomitant therapy with major interacting drugs, including **ALL** the following:
  - Renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren
  - Strong CYP3A inhibitors
  - Strong CYP3A inducers
  - Histamine H2 receptor antagonists
  - Proton pump inhibitors
  - Sensitive substrates of P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP)

(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 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: Immunoglobulin A Nephropathy (IgAN)**

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.

- ❑ 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., hepatotoxicity, acute kidney injury, severe hypotension, hyperkalemia)

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: Focal Segmental Glomerulosclerosis (FSGS) Without Nephrotic Syndrome**

Initial Authorization: 6 months

- ❑ Member is 8 years of age or older
- ❑ Provider is a nephrologist
- ❑ Member has a diagnosis of biopsy-proven focal segmental glomerulosclerosis (FSGS) or a documented pathogenic variant in a podocyte protein associated with FSGS **(submit biopsy or genetic test results)**
- ❑ Member does **NOT** have nephrotic syndrome (defined as proteinuria > 3.5 g/L and serum albumin < 30 g/L with or without edema)

(Continued on next page)

- ❑ Member's lab test results taken within the last 30 days must be submitted to document **ALL** the following:
  - ❑ Member has a urine protein-to-creatinine ratio ≥ 1.5 g/g
  - ❑ Member has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2
- ❑ 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)**
- ❑ Member has had a 90-day unsuccessful trial of 1 therapy for treatment of FSGS (e.g. high dose corticosteroid, tacrolimus, cyclosporine, rituximab; etc.) **(verified by chart notes and/or pharmacy paid claims)**
- ❑ Member is **NOT** currently receiving dialysis and has **NOT** undergone a kidney transplant
- ❑ Member will avoid concomitant therapy with major interacting drugs, including **ALL** the following:
  - Renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren
  - Strong CYP3A inhibitors
  - Strong CYP3A inducers
  - Histamine H2 receptor antagonists
  - Proton pump inhibitors
  - Sensitive substrates of P-glycoprotein (P-gp) and breast cancer resistance protein (BCRP)
- ❑ 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: Diagnosis: Focal Segmental Glomerulosclerosis (FSGS) Without Nephrotic Syndrome

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.

- ❑ 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., hepatotoxicity, acute kidney injury, severe hypotension, hyperkalemia)

(Continued on next page)

- ❑ 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™)

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

****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.*