

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: Oral: Initial: 200 mg once daily for 14 days. On day 15, increase to 400 mg once daily (recommended dose), if tolerated

Quantity Limit: 1 tablet 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

- 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

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- 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 m²
- 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)
- 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[™])

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

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

Medication being provided by Specialty Pharmacy – Proprium Rx
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*****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.****