

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: _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

Dosing Schedule: _____ Length of Therapy: _____

Diagnosis: _____ ICD Code: _____

Weight: _____ Date: _____

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 has been on a stable, maximized dose of a renin-angiotensin system (RAS) inhibitor ($\geq 50\%$ of maximum labeled dose), including either an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB), for at least 90 days (**verified 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
 - ❑ Urine protein-to-creatinine ratio is ≥ 1.5 g/g
 - ❑ eGFR ≥ 30 mL/min/1.73 m²
- ❑ Member does **NOT** have ALT or AST > 3 times the upper limit of normal (ULN), and provider will measure aminotransferase levels and total bilirubin monthly for the first 12 months after initiation, then every 3 months for the duration of treatment
- ❑ Requested medication will be discontinued permanently if ALT and/or AST levels rise to > 8 times the ULN if no other cause is found
- ❑ A negative pregnancy test is required prior to treatment initiation, monthly during treatment, and 1 month after the last dose of FilspariTM
- ❑ 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 the requested medication
- ❑ 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's renal function and potassium levels will be monitored frequently, especially for members with advanced kidney disease, those taking concomitant potassium-increasing drugs (e.g., potassium supplements, potassium-sparing diuretics), and those using potassium-containing salt substitutes
- ❑ 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 Tarpeyo[®] (budesonide delayed-release)

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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 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

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.