Clinical Policy: Sparsentan (Filspari)

Reference Number: PA.CP.PHAR.631
Effective Date: 06/2023
Last Review Date: 04/2026

Description
Sparsentan (Filspari™) is an endothelin and angiotensin II receptor antagonist.

FDA Approved Indication(s)
Filspari is indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of PA Health & Wellness® that Filspari is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Immunoglobulin A Nephropathy (must meet all)**:**

1. Diagnosis of IgAN confirmed via kidney biopsy;
2. Prescribed by or in consultation with a nephrologist;
3. Age ≥ 18 years;
4. Documentation of both of the following (a and b):
   a. Proteinuria of ≥ 0.5 g/day;
   b. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2;
5. Member meets both of the following, unless contraindicated or clinically significant adverse effects are experienced (a and b, *see Appendix D*):
   a. Failure of a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g., irbesartan, losartan, lisinopril, benazepril) for at least 12 weeks;
   b. RAAS inhibitor therapy dose was at maximum tolerated dose;
6. Filspari is not prescribed concurrently with RAAS inhibitors, endothelin receptor antagonists (ERAs), or aliskiren;
7. Dose does not exceed 400 mg (1 tablet) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Immunoglobulin A Nephropathy (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies;

2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. Decrease in UPCR from baseline;
   b. Reduction of proteinuria as evidence by a lower total urine protein per day from baseline;
3. Filspari is not prescribed concurrently with RAAS inhibitors, endothelin receptor antagonists (ERAs), or aliskiren;
4. If request is for a dose increase, new dose does not exceed 400 mg (1 tablet) per day
   Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.PHARM.01) applies.
   Approval duration: Duration of request or 12 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACEI: angiotensin-converting-enzyme inhibitor
ARB: angiotensin receptor blocker
eGFR: estimated glomerular filtration rate
ERA: endothelin receptor antagonist
FDA: Food and Drug Administration
IgAN: immunoglobulin A nephropathy
RAAS: renin-angiotensin-aldosterone system
UPCR: urine protein-to-creatinine ratio

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agentand may require prior authorization.

Drug Name	Maximum Dose
ACEIs	
benazepril (Lotensin®)	80 mg/day
captopril (Capoten®)	450 mg/day
enalapril (Vasotec®, Epaned®)	40 mg/day
fosinopril (Monopril®)	80 mg/day
lisinopril (Prinivil®, Zestril®, Qbrelis®)	80 mg/day
moexipril (Univasc®)	30 mg/day
perindopril (Aceon®)	16 mg/day
quinapril (Accupril®)	80 mg/day

Drug Name	Maximum Dose
ramipril (Altace®)	20 mg/day
trandolapril (Mavik®)	8 mg/day
ARBs	
azilsartan (Edarbi®)	80 mg/day
candesartan (Atacand®)	32 mg/day
eprosartan (Teveten®)	900 mg/day
irbesartan (Avapro®)	300 mg/day
losartan (Cozaar®)	100 mg/day
olmesartan (Benicar®)	40 mg/day
telmisartan (Micardis®)	80 mg/day
valsartan (Diovan®)	320 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): pregnancy; coadministration with ARBs, ERAs, or aliskiren
- Boxed warning(s): hepatotoxicity and embryo-fetal toxicity

Appendix D: General Information

- The 2025 Kidney Disease Improving Global Outcomes (KDIGO) recommends initial therapy with a RAAS inhibitor (ACEI or ARB) for all patients, except patients with contraindications such as low blood pressure, bilateral renal artery stenosis, or hyperkalemia, especially due to advanced CKD.Patients with IgAN who are considered high risk for progressive CKD despite maximum supportive care (defined as blood pressure control, reduction of proteinuria, and lifestyle modifications) may consider treatment with corticosteroids or immunosuppressive drugs; however, there is current uncertainty over the safety and efficacy of existing immunosuppressive treatment choices. For all patients in whom immunosuppression is being considered, a detailed discussion of the risks and benefits of each drug should be undertaken with the patient recognizing that adverse treatment effects are more likely in patients with eGFR < 50 mL/min/1.73 m^2.
- Filspari is only available through a restricted distribution program called the Filspari Risk Evaluation and Mitigation Strategies (REMS).

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IgAN	Initial treatment: 200 mg PO QD Maintenance: After 14 days, increase to recommended dose of 400 mg PO QD	400 mg/day

VI. Product Availability

Tablets: 200 mg, 400 mg

VII. References

1. Filspari Prescribing Information. San Diego, CA: Travere Therapeutics, Inc.; August 2025. Available at: https://www.filspari.com. Accessed January 14, 2026.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021 Oct;100(4S):S1-S276. doi: 10.1016/j.kint.2021.05.021.
3. ClinicalTrials.gov. A study of the effect and safety of sparsentan in the treatment of patients with IgA nephropathy (PROTECT). Available at: https://clinicaltrials.gov/ct2/show/NCT03762850. Accessed February 4, 2026.
4. Rovin BH, Barratt J, Heerspink HJL, et al.; DUPRO steering committee and PROTECT Investigators. Efficacy and safety of sparsentan versus irbesartan in patients with IgA nephropathy (PROTECT): 2-year results from a randomised, active-controlled, phase 3 trial. Lancet. 2023 Dec 2;402(10417):2077-2090.
5. Kidney Disease: Improving Global Outcomes (KDIGO) 2025 Clinical practice guideline for the management of immunoglobulin A nephropathy (IgAN) and immunoglobulin A vasculitis (IgAV). Kidney International (2025)108(Suppl 4S), S1–S71. Available at: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf.

Reviews, Revisions, and Approvals	Date
Policy created	05/2023
2Q 2024 annual review: for Appendix D, added Filspari REMS information; references reviewed and updated.	04/2024
2Q 2025 annual review: RT4: updated FDA Approved Indication section to reflect conversion to full approval and expanded indication; added to continuation of therapy requirement that Filspari is not prescribed concurrently with RAAS inhibitors, endothelin receptor antagonists (ERAs), or aliskiren; references reviewed and updated.	04/2025
2Q 2026 annual review: revised criterion for proteinuria ≥ 0.5 g/day per updated KDIGO 2025 guidance; references reviewed and updated.	04/2026