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Section:	Prescription Drugs	**Effective Date:**	July 1, 2026
Subsection:	Genitourinary Agents	**Original Policy Date:**	March 17, 2023
Subject:	Filspari	**Page:**	1 of 5

Last Review Date: June 11, 2026

Filspari

Description

Filspari (sparsentan) tablets

Background
Filspari (sparsentan) is a single molecule with antagonism of the endothelin type A receptor (ET_AR) and the angiotensin II type 1 receptor (AT_1R). Filspari has high affinity for both of these receptors over the endothelin type B and angiotensin II subtype 2 receptors. Endothelin-1 and angiotensin II are thought to contribute to the pathogenesis of primary immunoglobulin A nephropathy (IgAN) via the ET_AR and AT_1R, respectively (1).

Regulatory Status
FDA-approved indication: Filspari is an endothelin and angiotensin II receptor antagonist indicated: (1)

- to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.
- to reduce proteinuria in adult and pediatric patients aged 8 years and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome.

Filspari contains a boxed warning regarding hepatotoxicity and embryo-fetal toxicity. Filspari is only available through a restricted distribution program called the Filspari Risk Evaluation and Mitigation Strategies (REMS) because of these risks. Some endothelin receptor antagonists have caused elevations of aminotransferases, hepatotoxicity, and liver failure. Measure liver aminotransferases and total bilirubin prior to initiation of treatment and ALT and AST monthly for 12 months, then every 3 months during treatment. Filspari can cause major birth defects if used

during pregnancy. Pregnancy testing is required before, during, and after treatment. Patients who can become pregnant must use effective contraception prior to initiation of treatment, during treatment, and for two weeks after (1).

Prior to initiating treatment with Filspari, discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren (1).

People with IgA nephropathy that is causing high blood pressure may need to take medications that lower blood pressure and can also significantly slow the progression of kidney disease. Angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) have proven effective in slowing the progression of kidney disease (2).

Filspari also contains warnings regarding hypotension, acute kidney injury, hyperkalemia, and fluid retention (1).

The safety and efficacy of Filspari in pediatric patients less than 18 years of age with IgAN have not been established. The safety and efficacy of Filspari in pediatric patients less than 8 years of age with FSGS have not been established (1).

Related policies
Tarpeyo

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Filspari may be considered **medically necessary** if the conditions indicated below are met.

Filspari may be considered **investigational** for all other indications.

Prior-Approval Requirements

Diagnoses

Patient must have **ONE** of the following:

1. Primary immunoglobulin A nephropathy (IgAN)
    a. 18 years of age and older

b. Diagnosis has been confirmed by a kidney biopsy
c. Patient is at risk for disease progression indicated by proteinuria ≥ 1.0 g/day

2. Focal segmental glomerulosclerosis (FSGS)
   a. 8 years of age and older
   b. Diagnosis has been confirmed by a kidney biopsy **OR** genetic testing
   c. Patient has a urine protein to creatinine ratio (UPCR) ≥1.5 g/g
   d. Used to reduce proteinuria
   e. **NO** nephrotic syndrome

AND ALL of the following:

a. Inadequate treatment response, intolerance, or contraindication to an ACE inhibitor or ARB
b. eGFR ≥ 30 mL/min/1.73 m2
c. Prescribed by or recommended by a nephrologist
d. Patient and prescriber are enrolled in the Filspari REMS program
e. Prescriber agrees to monitor AST, ALT, and total bilirubin before initiating treatment and monthly for the first 12 months
f. Females of reproductive potential **only**: prescriber agrees not to initiate treatment until after confirmation of a negative pregnancy test
g. Females of reproductive potential **only**: patient will be advised to use effective contraception before the initiation of treatment, during treatment, and for 2 weeks after the last dose
h. **NOT** used in combination with angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren

Prior – Approval *Renewal* Requirements

Diagnoses

Patient must have the following:

1. Primary immunoglobulin A nephropathy (IgAN)
   a. 18 years of age and older
2. Focal segmental glomerulosclerosis (FSGS)
   a. 8 years of age and older

AND ALL of the following:

a. Decrease in proteinuria
b. Prescriber agrees to monitor AST, ALT, and total bilirubin every 3 months during treatment
c. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment and for 2 weeks after the last dose
d. **NOT** used in combination with angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Diagnosis	Maximum Daily Dose
Primary immunoglobulin A nephropathy (IgAN)	400 mg per day
Focal segmental glomerulosclerosis (FSGS)	800 mg per day

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Filspari is an endothelin and angiotensin II receptor antagonist indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) or reduce proteinuria in patients with focal segmental glomerulosclerosis (FSGS). Filspari contains a boxed warning regarding hepatotoxicity and embryo-fetal toxicity. Filspari is only available through a restricted distribution program called the Filspari Risk Evaluation and Mitigation Strategies (REMS) because of these risks. The safety and efficacy of Filspari in pediatric patients less than 18

years of age with IgAN have not been established. The safety and efficacy of Filspari in pediatric patients less than 8 years of age with FSGS have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Filspari while maintaining optimal therapeutic outcomes.

References

1. Filspari [package insert]. San Diego, CA: Travere Therapeutics, Inc.; April 2026.
2. IgA Nephropathy. National Institute of Diabetes and Digestive and Kidney Diseases. November 2015. https://www.niddk.nih.gov/health-information/kidney-disease/iga-nephropathy.

Policy History

Date	Action
March 2023	Addition to PA
June 2023	Annual review
March 2024	Annual review
June 2024	Annual review
March 2025	Annual editorial review and reference update
June 2025	Annual review
August 2025	Per FEP, replaced UPCR with proteinuria in requirements
September 2025	Annual review
March 2026	Annual review and reference update
May 2026	Per PI update, added indication of focal segmental glomerulosclerosis (FSGS). Changed contraception requirement to 2 weeks after the last dose
June 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.