

Federal Employee Program.

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5.55.004

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Genitourinary Agents Original Policy Date: March 17, 2023

Subject: Filspari Page: 1 of 5

Last Review Date: September 19, 2025

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 to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression (1).

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 in 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 one month after (1).

5.55.004

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Genitourinary Agents Original Policy Date: March 17, 2023

Subject: Filspari Page: 2 of 5

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 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

Age 18 years of age and older

Diagnosis

Patient must have the following:

Primary immunoglobulin A nephropathy (IgAN)

AND ALL of the following:

a. Diagnosis has been confirmed by a kidney biopsy

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Genitourinary Agents Original Policy Date: March 17, 2023

Subject: Filspari Page: 3 of 5

b. Patient is at risk for disease progression indicated by proteinuria ≥ 1.0 g/day

- c. Inadequate treatment response, intolerance, or contraindication to an ACE inhibitor or ARB
- d. eGFR ≥ 30 mL/min/1.73 m2
- e. Prescribed by or recommended by a nephrologist
- f. Patient and prescriber are enrolled in the Filspari REMS program
- g. Prescriber agrees to monitor AST, ALT, and total bilirubin before initiating treatment and monthly for the first 12 months
- h. Females of reproductive potential **only**: prescriber agrees not to initiate treatment until after confirmation of a negative pregnancy test
- Females of reproductive potential only: patient will be advised to use effective contraception before the initiation of treatment, during treatment, and for 1 month after the last dose
- NOT used in combination with angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren

Prior - Approval Renewal Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Primary immunoglobulin A nephropathy (IgAN)

AND ALL of the following:

- a. Decrease in proteinuria
- b. Prescriber agrees to monitor AST, ALT, and total bilirubin every 3 months during treatment
- Females of reproductive potential only: patient will be advised to use effective contraception during treatment and for 1 month after the last dose
- d. **NOT** used in combination with angiotensin receptor blockers (ARBs), endothelin receptor antagonists (ERAs), or aliskiren

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Genitourinary Agents Original Policy Date: March 17, 2023

Subject: Filspari Page: 4 of 5

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 400 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) at risk for disease progression. 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 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.; November 2024.
- 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

5.55.004

Section: Prescription Drugs Effective Date: October 1, 2025

Subsection: Genitourinary Agents Original Policy Date: March 17, 2023

Subject: Filspari Page: 5 of 5

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.