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

Last Review Date: June 15, 2023

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 reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g (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).

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

b. Patient is at risk of rapid disease progression indicated by a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g
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
i. 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
j. **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 urine protein-to-creatinine ratio (UPCR)
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 1 month 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 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 reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g. 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.; February 2023.
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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 15, 2023 and is effective on July 1, 2023.