Filspari (sparsentan)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Filspari (sparsentan) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Filspari (sparsentan) is indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk of rapid disease progression..

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests:
    a. Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
    b. Chart notes, medical records or laboratory values indicating that the member is at risk for disease progression defined by proteinuria greater than or equal to 0.5 g/day
2. For continuation requests: Chart notes, medical records or laboratory values supporting positive clinical response.

Prescriber Specialties

Filspari must be prescribed by or in consultation with a nephrologist.

Criteria for Initial Approval

Primary Immunoglobulin A Nephropathy (IgAN)

Authorization of 9 months may be granted when all of the following criteria are met:

1. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy
2. Member is 18 years of age or older
3. Member is at risk of rapid disease progression defined by proteinuria greater than or equal to 0.5 g/day Member has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m^2
4. Member has received a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitors [ACEIs] or angiotensin II receptor blockers [ARBs]) for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to RAS inhibitors
5. The requested medication will not be used in combination with Tarpeyo (budesonide delayed release), Fabhalta (iptacopan), Vanrafia (atrasentan), or Voyxact (sibeprenlimab-szsi)

Continuation of Therapy

Primary Immunoglobulin A Nephropathy (IgAN)

Authorization of 12 months may be granted for all members who are using the requested medication for proteinuria reduction in primary immunoglobulin A nephropathy when the following criteria are met:

1. Member has an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73m^2
2. Member achieves or maintains a positive clinical response as evidenced by one of the following:
   i. Reduction in proteinuria from baseline
   ii. Reduction in UPCR from baseline

Filspari is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

Medication	Standard Limit	FDA Recommended Dosing
Filspari (sparsentan) 200 mg oral tablets	30 tablets per 30 days	Initiate treatment at 200 mg orally once daily. After 14 days, increase to the recommended dose of 400 mg once daily, as tolerated.
Filspari (sparsentan) 200 mg oral tablets		

CLINICAL RATIONALE

Filspari (sparsentan) is an oral, once-daily, endothelin and angiotensin II receptor antagonist indicated for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression. Blockade of endothelin-1 and angiotensin II pathways has been shown to reduce proteinuria, protect podocytes, and prevent glomerulosclerosis in IgAN. Currently, initial treatment for IgAN consists of off-label use with angiotensin converting enzyme inhibitors (ACEi) or angiotensin II type 1

receptor blockers (ARB) based on their mechanism of slowing chronic kidney disease progression. Filspari (sparsentan) is the first FDA-approved non-immunosuppressant medication for IgAN.

Efficacy

The efficacy and safety of Filspari (sparsentan) were evaluated in an unpublished, randomized, double-blind, active-controlled, multicenter, global clinical trial (PROTECT) in 281 adult patients (69% male; 62% White, 35% Asian; mean age 46 years) with biopsy-proven IgAN, eGFR ≥ 30 mL/min/1.73 m^2 and total urine protein ≥ 1 g/day who were on a maximized dose of renin-angiotensin system (RAS) inhibitor treatment that was at least 50% of maximum labeled dose (Filspari prescribing information, 2023). Patients were assigned in a 1:1 ratio to either Filspari (sparsentan) 400mg or irbesartan 300mg once daily. At baseline, mean eGFR was 56 mL/min/1.73 m2, 77% had a history of hypertension, 12% had a history of diabetes and 53% had hematuria. Rescue immunosuppressive treatment could be initiated per investigator discretion but use of a sodium-glucose cotransporter-2 (SGLT2) inhibitor was prohibited. The primary endpoint was relative change from baseline in urine protein creatinine ratio (UPCR) at week 36.

Patients treated with Filspari (sparsentan) had a 45% reduction in UPCR at 9 months compared with a 15% reduction for patients treated with irbesartan (treatment difference 30%, $p < 0.0001$) (Filspari prescribing information, 2023). Treatment effect on UPCR was consistent across subgroups such as age, sex, race, and baseline eGFR and proteinuria levels. Rescue immunosuppressive treatment was initiated in 1.4% and 5.7% of Filspari (sparsentan) and irbesartan patients, respectively.

In the two-year confirmatory secondary endpoint results, eGFR chronic 2-year slope was −2.7 mL/min/1.73 m^2 per year in the Filspari group versus −3.8 mL/min/1.73 m^2 per year in the control group (95% CI 0.1 to 2.1; p=0.037. While the total 2-year slope was lower in the Filspari group, the result was not statistically significant (treatment difference - 1.0 mL/min/1.73 m^2 per year [95% CI −0.03 to 1.94; p=0.058]). The significant reduction in proteinuria at 36 weeks with Filspari was maintained throughout the study period and at 110 weeks, proteinuria was 40% lower in the sparsentan group than in the irbesartan group (−42.8%, [95% CI −49.8 to −35.0] with sparsentan versus −4.4%, [95% CI −15.8 to 8.7] with irbesartan). No new safety concerns were identified.

Filspari received full FDA approval in September 2024 based on long-term confirmatory results from the PROTECT study demonstrating that Filspari significantly slowed kidney function decline over 2 years compared to irbesartan. In the final analysis of the 404 randomized patients, Filspari significantly reduced the rate of decline in kidney function from baseline to Week 110 compared to irbesartan. In the ITT analysis included in the label, the mean eGFR slope from baseline to Week 110 was -3.0 mL/min/1.73 m^2/year for Filspari and -4.2 mL/min/1.73 m^2/year for irbesartan, corresponding to a statistically significant treatment effect of 1.2 mL/ min/1.73 m^2/year (p=0.0168). The positive treatment effects on proteinuria that were observed at Week 36 were durable out to the two-year measurement period. Additional results from the PROTECT Study demonstrated the benefit of Filspari on absolute eGFR accrued over time and by Week 110 resulted in a 3.8 mL/min/1.73 m^2 difference in the mean change from baseline between Filspari and irbesartan.

Safety

Although Filspari (sparsentan) did not demonstrate severe liver toxicity in the PROTECT trial, the FDA has required a Risk Evaluation and Mitigation Strategy (REMS) program for risk of hepatotoxicity and embryo-fetal toxicity like other endothelin receptor antagonists (ERA). Other warnings include hypotension, acute kidney injury, hyperkalemia, and fluid retention. The most common adverse events associated with Filspari (sparsentan) in trials include peripheral edema (14%), hypotension (14%), dizziness (13%), hyperkalemia (13%), anemia (5%), acute kidney injury (4%), and transaminase elevations (2.5%). Due to its mechanism of action, Filspari should not be co-administered with RAS inhibitors, ERAs or aliskiren. Filspari is a CYP3A4 substrate and concomitant use with strong CYP3A4 inducers or inhibitors should be avoided.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Filspari [package insert]. San Diego, CA: Travere Therapeutics, Inc.; August 2025.
- Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidney Int. 2025 Oct; 108 (4S):S1-S71.A Randomized, Multicenter, Double-blind, Parallel-group, Active-control Study of the Efficacy and Safety of Sparsentan for the Treatment of Immunoglobulin A Nephropathy. clinicaltrials.gov. Published February 1, 2023.
- Rovin BH, Barratt J, Heerspink HFL, et al. Efficacy and safety of sparsentan versus irbesartan in patients with IgA nephropathy (PROTECT): 2-year results from a randomisded, active-controlled, phase 3 trial. Lancet. 2023 December;402(10417);2077-5090.

POLICY HISTORY

Policy #: 05.04.94
Original Effective Date: May 31, 2023
Reviewed: January 2026
Revised: January 2026
Current Effective Date: March 10, 2026