Drug Coverage Policy

Effective Date 5/1/2026
Coverage Policy Number.....IP0565
Policy Title.....Filspari

Nephrology – Filspari

- Filspari™ (sparsentan tablets – Travere)

INSTRUCTIONS FOR USE

The following Coverage Policy applies to health benefit plans administered by Cigna Companies. Certain Cigna Companies and/or lines of business only provide utilization review services to clients and do not make coverage determinations. References to standard benefit plan language and coverage determinations do not apply to those clients. Coverage Policies are intended to provide guidance in interpreting certain standard benefit plans administered by Cigna Companies. Please note, the terms of a customer's particular benefit plan document [Group Service Agreement, Evidence of Coverage, Certificate of Coverage, Summary Plan Description (SPD) or similar plan document] may differ significantly from the standard benefit plans upon which these Coverage Policies are based. For example, a customer's benefit plan document may contain a specific exclusion related to a topic addressed in a Coverage Policy. In the event of a conflict, a customer's benefit plan document always supersedes the information in the Coverage Policies. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan document. Coverage determinations in each specific instance require consideration of 1) the terms of the applicable benefit plan document in effect on the date of service; 2) any applicable laws/regulations; 3) any relevant collateral source materials including Coverage Policies and; 4) the specific facts of the particular situation. Each coverage request should be reviewed on its own merits. Medical directors are expected to exercise clinical judgment where appropriate and have discretion in making individual coverage determinations. Where coverage for care or services does not depend on specific circumstances, reimbursement will only be provided if a requested service(s) is submitted in accordance with the relevant criteria outlined in the applicable Coverage Policy, including covered diagnosis and/or procedure code(s). Reimbursement is not allowed for services when billed for conditions or diagnoses that are not covered under this Coverage Policy (see "Coding Information" below). When billing, providers must use the most appropriate codes as of the effective date of the submission. Claims submitted for services that are not accompanied by covered code(s) under the applicable Coverage Policy will be denied as not covered. Coverage Policies relate exclusively to the administration of health benefit plans. Coverage Policies are not recommendations for treatment and should never be used as treatment guidelines. In certain markets, delegated vendor guidelines may be used to support medical necessity and other coverage determinations.

OVERVIEW

Filspari, an endothelin and angiotensin II receptor antagonist, is indicated to slow kidney function decline in adults with **primary immunoglobulin A nephropathy** (IgAN) who are at risk of rapid disease progression.[1]

Filspari is contraindicated for use with renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), or aliskiren.[1] RAAS inhibitors, ERAs, and/or aliskiren must be discontinued prior to initiation of Filspari.

Clinical Efficacy
The efficacy of Filspari is being assessed in a Phase III trial in adults with biopsy-proven IgAN, proteinuria ≥ 1.0 g/day at screening, and estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2 (PROTECT, n = 404).[4] Additionally patients were receiving the maximum tolerated dose (at least one-half of the maximum labeled dose) of an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) for ≥ 12 weeks prior to study entry and had blood pressure of ≤ 150/100 mmHg (managed according to standard of care). Patients with use of immunosuppressive medications (including corticosteroids for > 2 weeks within 3 months of screening), chronic kidney disease (CKD) in addition to IgAN, or IgAN secondary to other conditions were excluded. Per study protocol, patients discontinued their ACEi or ARB 1 day prior to the start of Filspari.[2]

The primary efficacy endpoint was the change from baseline in urine protein-to-creatinine ratio (based on 24-hour urine sample) [UPCR] at Week 36.[4] The primary analysis was based on an interim data cutoff of August 1, 2021. At Week 36, the primary endpoint was significantly greater with Filspari vs. irbesartan in the interim analysis set; the geometric least squares mean percent change in UPCR from baseline was -49% vs. -15%, respectively. This resulted in a statistically significant relative reduction from baseline in UPCR for the Filspari vs. irbesartan group (least squares mean ratio 0.59; 95% confidence interval [CI]: 0.51, 0.69; P < 0.0001), corresponding to a 41% relative reduction with Filspari.

Several exploratory endpoints also favored Filspari over irbesartan.[4] At the interim analysis (Week 36), the proportion of patients in the Filspari group who achieved partial proteinuria remission (< 1 g/day) was significantly higher with Filspari vs. irbesartan (70% vs. 44%, respectively) and numerically more patients in the Filspari vs. irbesartan group (21% vs. 8%, respectively) achieved complete proteinuria remission (< 0.3 g/day) at Week 36.

Following the 36 week randomized, treatment period, patients were followed until the patient reached Week 110.[5] The significant reduction in proteinuria at Week 36 was maintained through Week 110. The UPCR at Week 110 was 40% lower in the Filspari group compared to the irbesartan group (-42·8% with Filspari versus -4·4% with irbesartan). Filspari also reduced the rate of decline in kidney function from baseline to Week 110 when compared with irbesartan (-3.0 mL/min/1.73 m^2 per year for Filspari vs. 4.2 mL/min/1.73 m^2 per year for irbesartan) with a corresponding treatment effect of 1.2 mL/min/1.73 m^2 per year (P = 0.0168).

Guidelines
KDIGO clinical practice guidelines for the management of IgAN and immunoglobulin A vasculitis (2025) recommend patients who are at risk of progressive kidney function loss with IgAN to be treated with RAS inhibitor or Filspari (sparsentan tablets) with or without a SGLT2 inhibitor.2 Filspari should not be prescribed with a RAS inhibitor. It is also recommended that a 9-month course of Tarpeyo (budesonide delayed-release capsules) be considered for patients with a risk of progressive kidney function loss with IgAN. Therapeutic strategies that minimize or avoid systemic glucocorticoid exposure are considered areas of priority for research to improve treatment and outcomes in patients with IgAN. Voyxact, Fabhalta (iptacopan capsules), and Vanrafia (atrasentan tablets) were noted as investigative treatments with no guideline recommendations.

The goal of treatment is to prevent progressive kidney function loss.2 The only validated biomarker to guide clinical decision-making is urine protein excretion, which should be maintained

< 0.5 g/day and ideally < 0.3 g/day. Following a biopsy-confirmed diagnosis of IgAN, the primary focus of treatment should include RAS inhibitors or Filspari with or without SGLT2 inhibitor, blood pressure control, cardiovascular risk minimization, and adherence to lifestyle advice. Additional treatment should be considered if the patient has proteinuria ≥ 0.5 g/day while on or off treatment. In patients who remain at high risk of progressive CKD despite maximal supportive care, a 6- to 9-month course of glucocorticoid therapy should be considered. However, the guidelines recommend that glucocorticoid use in IgAN should be used with extreme caution or avoided in patients with an eGFR < 30 mL/minute/1.73 m2, diabetes, obesity (body mass index > 30 kg/m2), latent infections (e.g., tuberculosis, viral hepatitis), secondary disease (e.g., cirrhosis), active peptic ulceration, uncontrolled psychiatric illness, and severe osteoporosis.

Safety
Filspari has a Black Box Warning and Risk Evaluation and Mitigation Strategy (REMS) program around hepatotoxicity and embryo-fetal toxicity.[1,] A Risk Evaluation and Mitigation Strategy (REMS) program is in place for hepatotoxicity.[3] The one objective of the REMS are is to monitor for elevations in liver enzymes in patients exposed to Filspari.

Coverage Policy

Policy Statement
Prior Authorization is required for benefit coverage of Filspari. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Filspari as well as the monitoring required for adverse events and long-term efficacy, approval requires Filspari to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Documentation: Documentation is required where noted in the criteria as **[documentation required]**. Documentation may include, but not limited to, chart notes, laboratory tests, claims records, and/or other information. All documentation must include patient-specific identifying information.

Filspari is considered medically necessary when the following are met:

FDA-Approved Indication

1. **Primary Immunoglobulin A Nephropathy.** Approve for the duration noted if the patient meets ONE of the following (A or B):
   - **A.** Initial Therapy. Approve for 1 year if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The diagnosis has been confirmed by biopsy **[documentation required]**; AND
     - **iii.** Patient is at high risk of disease progression, defined by meeting BOTH the following criteria (a and b):
       - **a.** Patient meets ONE of the following [(1) or (2)]:
         (1) Proteinuria ≥ 0.5 g/day **[documentation required]**; OR
         (2) Urine protein-to-creatinine ratio ≥ 0.8 g/g **[documentation required]**; AND
       - **b.** Patient has received the maximum or maximally tolerated dose of ONE of the following for ≥ 12 weeks prior to starting Filspari [(1) or (2)]:
         (1) Angiotensin converting enzyme inhibitor; OR
         (2) Angiotensin receptor blocker; AND

iv. According to the prescriber, patient has received ≥ 3 months of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification; AND
v. Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
vi. The medication will not be used in combination with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists, or aliskiren; AND
Note: Examples of angiotensin converting enzyme inhibitors include but are not limited to lisinopril, fosinopril, enalapril, benazepril. Examples of angiotensin receptor blockers include but are not limited to irbesartan, losartan, candesartan, valsartan.
vii. The medication is prescribed by or in consultation with a nephrologist.

B) Patient is Currently Receiving Filspari. Approve for 1 year if the patient meets the following (i, ii, iii, iv, v, and vi):
i. Patient is ≥ 18 years of age; AND
ii. The diagnosis has been confirmed by biopsy **[documentation required]**; AND
iii. According to the prescriber, patient has had a response to Filspari,; AND
Note: Examples of a response are a reduction in urine protein-to-creatinine ratio from baseline, reduction in proteinuria from baseline.
iv. Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
v. The medication is not being used in combination with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists, or aliskiren; AND
Note: Examples of angiotensin converting enzyme inhibitors include but are not limited to lisinopril, fosinopril, enalapril, benazepril. Examples of angiotensin receptor blockers include but are not limited to irbesartan, losartan, candesartan, valsartan.
vi. The medication is prescribed by or in consultation with a nephrologist.

Conditions Not Covered

Filspari for any other use is considered not medically necessary, including the following (this list may not be all inclusive; criteria will be updated as new published data are available):

1. **Concurrent Use with Other Medications Indicated for the Treatment of Immunoglobulin A Nephropathy (e.g., Fabhalta and Vanrafia).**
The requested medication should not be administered in combination with other medications indicated for immunoglobulin A nephropathy. Combination therapy is generally not recommended due to a lack of controlled clinical trial data supporting additive efficacy.

References

1. Filspari™ tablets [prescribing information]. San Diego, CA: Travere; August 2025.
2. Kidney Diseases: Improving Global Outcomes (KDIGO) 2025 clinical practice guidelines for the management of immunoglobulin A nephropathy (IgAN) and immunoglobulin A vasculitis (IgAV). Available at: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf. Accessed on January 28, 2026.
3. The Filspari™ REMS (Risk Evaluation and Mitigation Strategy). Available at: https://filsparirems.com/#Main. Accessed on: January 28, 2026.
4. Heerspink HJL, Radhakrishnan J, Alpers CE, et al. Sparsentan in patients with IgA nephropathy: a prespecified interim analysis from a randomised, double-blind, active-controlled clinical trial. *Lancet*. 2023;401(10388):1584-1594.

5. Rovin BH, Barratt J, Heerspink HJL, et al. 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;402(10417):2077-2090.

Revision Details

Type of Revision	Summary of Changes	Date
Annual Review	**Primary Immunoglobulin A Nephropathy.** (1) Added 'Patient is currently receiving Filspari' criteria. (2) Updated high risk of disease progression criteria.	06/01/2024
Selected Revision	**Primary Immunoglobulin A Nephropathy:** The criterion requiring that the patient is at high risk of disease progression, defined by ONE of the following: urine-to-protein-creatinine ratio ≥ 1.5 g/g OR proteinuria ≥ 1 g/day was revised to require that the patient is at high risk of disease progression, defined by urine-to-protein-creatinine ratio ≥ 0.8 g/g OR proteinuria ≥ 0.5 g/day. The approval duration was changed to 1 year for initial and continuation therapy (previously the approval duration was 9 months for initial and 1 year for continuation therapy).	12/15/2024
Annual Revision	No criteria changes.	05/15/2025
Selected Revision	**Primary Immunoglobulin A Nephropathy. Added** documentation requirements.	07/01/2025
Selected Revision	**Updated policy statement** **Conditions Not Recommended for Approval:** Added new condition regarding concomitant use with other medications indicated for the treatment of immunoglobulin A nephropathy.	09/01/2025
Annual Revision	No criteria changes.	5/1/2026

The policy effective date is in force until updated or retired.