PRIOR AUTHORIZATION POLICY

POLICY: Nephrology – Filspari Prior Authorization Policy
- Filspari™ (sparsentan tablets – Travere)

REVIEW DATE: 04/22/2026

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.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Filspari, an endothelin and angiotensin II receptor antagonist, is indicated for the following conditions:[1]

- To reduce proteinuria in adult and pediatric patients ≥ 8 years of age **with focal segmental glomerulosclerosis** (FSGS) without nephrotic syndrome.
- To slow kidney function decline in adults with **primary immunoglobulin A nephropathy** (IgAN) who are at risk of rapid disease progression.

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

Clinical Efficacy

FSGS

The DUPLEX trial (n=371) evaluated Filspari versus irbesartan in patients ages 8 to75 with FSGS without known secondary causes for 108 weeks.[7] The surrogate endpoint at 36 weeks was partial remission of proteinuria (UPCR ≤1.5 g/g and >40% reduction from baseline), and the primary efficacy endpoint was eGFR slope at 108 weeks. At Week 36, partial remission of proteinuria was significantly higher with Filspari (42.0%) vs. irbesartan (26.0%)[P=0.009], a response sustained through Week 108. However, at the final analysis (Week 108), there were no significant between-group differences in eGFR slope: the total slope difference was 0.3 mL/min/1.73 m²/year, and the chronic slope difference was 0.9 mL/min/1.73 m²/year. Mean eGFR change from baseline to Week 112 was - 10.4 mL/min/1.73 m² with Filspari vs. - 12.1 mL/min/1.73 m² with irbesartan (treatment difference of 1.8 mL/min/1.73 m²).

IgAN
The PROTECT trial (n=404) evaluated Filspari in adults with biopsy-proven IgAN, proteinuria ≥1.0 g/day, and eGFR ≥30 mL/min/1.73 m² who were on stable angiotensin-converting enzyme inhibitors (ACEi)/ARB therapy.[4] Patients with recent immunosuppressive use or secondary IgAN were excluded. At Week 36, Filspari demonstrated a 49% reduction in UPCR from baseline compared with 15% for irbesartan, representing a statistically significant 41% relative reduction (P<0.0001). Exploratory endpoints also favored Filspari: 70% of Filspari patients vs. 44% of irbesartan patients achieved partial proteinuria remission (<1 g/day), and 21% vs. 8%, respectively, achieved complete 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

FSGS
KDIGO clinical practice guidelines for the management of glomerular diseases (2021) recommend that all patients should receive RAS blockade immediately for symptomatic benefit regardless of FSGS subtype.[6] Guidelines recommend high-dose oral glucocorticoids (prednisone 0.5-2.0 mg/kg/day) as first-line treatment for primary FSGS, continued until complete remission or up to a maximum of 16 weeks. For steroid-resistant primary FSGS, calcineurin inhibitors (cyclosporine or tacrolimus) should be given for ≥6 months. Patients resistant to both steroids and calcineurin inhibitors should be referred to specialized centers for rebiopsy, alternative treatment, or clinical trial enrollment. For secondary FSGS and FSGS of undetermined cause, immunosuppression should not be used; management focuses on RAS blockade, blood pressure control, and treating underlying causes. The goal of treatment is remission, which is defined as a reduction of proteinuria to < 0.3 g/day or protein-creatinine ration < 300 mg/g, stable serum creatinine and serum albumin >3.5 g/dL

IgAN
KDIGO clinical practice guidelines for the management of IgAN and immunoglobulin A vasculitis (2025) recommend 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.[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. 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. Additional treatment should be considered if the patient has proteinuria ≥ 0.5 g/day (or equivalent) while on or off treatment.

Safety
Filspari has a Black Box Warning 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 is to monitor for elevations in liver enzymes in patients exposed to Filspari.

POLICY STATEMENT
Prior Authorization is recommended for prescription 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.

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is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

1. **Focal Segmental Glomerulosclerosis.** Approve for 1 year if the patient meets ONE of the following (A or B):
   A) Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, vi, and vii):
      i. Patient is ≥ 8 years of age; AND
      ii. Patient has ONE of the following (a or b):
         a) Patient has a biopsy confirming primary disease; OR

b) Patient has a genetic variant associated with the disease; AND
Note: Examples of genetic variants associated with focal segmental glomerulosclerosis include monogenic variants in podocyte proteins (*CD2AP*, *INF2*, *LMX1B*, *NPHS1*, *NPHS2*, *TRPC6*, and *WT1)*, *COL4A3-5* variants, or high-risk *APOL1* variants.

iii. Patient does not have nephrotic syndrome; AND
Note: Prescence of nephrotic syndrome is a proteinuria > 3.5 g/L and serum albumin < 30 g/L with or without edema.

iv. Patient has a urine protein-to-creatinine ratio ≥ 1.5 g/g; 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 include but are not limited to lisinopril, fosinopril, enalapril, benazepril, irbesartan, losartan, candesartan, valsartan, ambrisentan, bosentan.

vii. The medication is prescribed by or in consultation with a nephrologist; OR

B) Patient is Currently Receiving Filspari. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):

i. Patient is ≥ 8 years of age; AND

ii. Patient has had a response to the requested medication; AND
Note: Example of a response is a reduction in urine protein-to-creatinine ratio from baseline.

iii. Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND

iv. 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 include but are not limited to lisinopril, fosinopril, enalapril, benazepril, irbesartan, losartan, candesartan, valsartan, ambrisentan, bosentan.

v. The medication is prescribed by or in consultation with a nephrologist.

2. Primary Immunoglobulin A Nephropathy. Approve for 1 year if the patient meets ONE of the following (A or B):

A) Initial Therapy. Approve 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; AND

iii. Patient is at high risk of disease progression, defined by meeting BOTH of the following (a and b):

a) Patient meets ONE of the following [(1) or (2)]:

(1) Proteinuria ≥ 0.5 g/day; OR

(2) Urine protein-to-creatinine ratio ≥ 0.5 g/g; AND

b) Patient has received the maximum or maximally tolerated dose of ONE of the following for ≥ 12 weeks prior to starting the medication [(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 include but are not limited to lisinopril, fosinopril, enalapril, benazepril, irbesartan, losartan, candesartan, valsartan, ambrisentan, bosentan.

vii. The medication is prescribed by or in consultation with a nephrologist; OR

B) Patient is Currently Receiving Filspari. Approve if the patient meets ALL of 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; AND

iii. Patient has had a response to the requested medication; 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 include but are not limited to lisinopril, fosinopril, enalapril, benazepril, irbesartan, losartan, candesartan, valsartan, ambrisentan, bosentan.

vi. The medication is prescribed by or in consultation with a nephrologist.

CONDITIONS NOT COVERED

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is(are) considered not medically necessary for ANY other use(s) 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; April 2026.
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 April 14, 2026.
3. The Filspari™ REMS (Risk Evaluation and Mitigation Strategy). Available at: https://filsparirems.com/#Main. Accessed on: April 17, 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.
6. Kidney Diseases: Improving Global Outcomes (KDIGO) 2021 clinical practice guidelines for the management of glomerular disease. Available at: https://kdigo.org/wp-content/uploads/2024/05/KDIGO-2021-Glomerular-Diseases-Guideline_English_2024-Chapter-Updates.pdf. Accessed on April 14, 2026.
7. Rheault MN, Alpers CE, Barratt J, et al. Sparsentan versus irbesartan in focal segmental glomerulosclerosis. *N Engl J Med*. 2023;389(26):2436-2445.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	02/28/2024
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).	10/02/2024
Annual Revision	No criteria changes.	02/26/2025
Selected Revision	**Conditions Not Covered** **:** Added new condition regarding concomitant use with other medications indicated for the treatment of immunoglobulin A nephropathy.	07/16/2025
Update	**Overview:** The safety section was updated to reflect changes in the REMs program. No criteria changes.	10/08/2025
Annual Revision	No criteria changes.	02/04/2026
Early Annual Revision	**Focal Segmental Glomerulosclerosis:** This was added as a new condition of approval. **Primary Immunoglobulin A Nephropathy:** The criterion requiring that the patient is at high risk of disease progression, defined by ONE of the following: urine protein-to-creatinine ratio ≥ 0.8 g/g OR proteinuria ≥ 0.5 g/day was modified to require that the patient is at high risk of disease progression, defined by urine protein-to-creatinine	04/22/2026

	ratio ≥ 0.5 g/g OR proteinuria ≥ 0.5 g/day. The Note of examples of angiotensin converting enzyme inhibitors or angiotensin receptor blockers was modified to examples include but are not limited to lisinopril, fosinopril, enalapril, benazepril, irbesartan, losartan, candesartan, valsartan, ambrisentan, bosentan.	