Clinical Policy: Sparsentan (Filspari)

Reference Number: CP.PHAR.631
Effective Date: 06.01.23
Last Review Date: 08.26
Line of Business: Commercial, HIM/ICHRA, Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Sparsentan (Filspari®) is an endothelin and angiotensin II receptor antagonist.

FDA Approved Indication(s)

Filspari is indicated:

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

Policy/Criteria

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation® that Filspari is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Immunoglobulin A Nephropathy (must meet all)**:**

1. Diagnosis of IgAN confirmed via kidney biopsy;
2. Prescribed by or in consultation with a nephrologist;
3. Age ≥ 18 years;
4. Documentation of both of the following (a and b):
   a. Proteinuria of ≥ 0.5 g/day;
   b. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2;
5. Member meets both of the following, unless contraindicated or clinically significant adverse effects are experienced (a and b, *see Appendix D*):*
   **For Illinois HIM requests, the step therapy requirements below do not apply per IL HB 5395*
   a. Failure of a renin-angiotensin-aldosterone system (RAAS) inhibitor (e.g., irbesartan, losartan, lisinopril, benazepril) for at least 12 weeks;
   b. RAAS inhibitor therapy dose was at least 50% of maximum labeled dose;
6. Filspari is not prescribed concurrently with RAAS inhibitors, endothelin receptor antagonists (ERAs), or aliskiren;
7. Failure of a 12 week trial of a sodium-glucose cotransporter-2 (SGLT2) inhibitor (e.g., empagliflozin, dapagliflozin) at up to maximally indicated doses, unless clinically significant adverse effects are experienced or all are contraindicated;*
   **For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*

8. Dose does not exceed both of the following (a and b):
   a. 400 mg per day;
   b. 1 tablet per day.

Approval duration: 12 months

B. Focal Segmental Glomerulosclerosis (must meet all)**:**
1. Diagnosis of FSGS as evidenced by one of the following (a or b):
   a. Confirmed via kidney biopsy;
   b. Documentation of a genetic mutation in a podocyte protein associated with FSGS (e.g. NPHS1, NPHS2, PLCE1, CD2AP, TRPC6, ACTN4, INF2, LMX1B, WT1);
2. Member does not have nephrotic syndrome (see *Appendix D*);
3. Prescribed by or in consultation with a nephrologist;
4. Age ≥ 8 years;
5. Documentation of both of the following (a and b):
   a. Urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g;
   b. eGFR ≥ 30 mL/min/1.73 m^2;
6. Member meets both of the following, unless contraindicated or clinically significant adverse effects are experienced (a and b, *see Appendix* D):*
   **For Illinois HIM requests, the step therapy requirements above do not apply per IL HB 5395*
   a. Failure of a RAAS inhibitor (e.g., irbesartan, losartan, lisinopril, benazepril) for at least 12 weeks;
   b. RAAS inhibitor therapy dose was at least 50% of maximum labeled dose;
7. Filspari is not prescribed concurrently with RAAS inhibitors, ERAs, or aliskiren;
8. Dose does not exceed one of the following (a or b):
   a. Weight ≤ 50 kg: Both of the following (i and ii):
      i. 400 mg per day;
      ii. 1 tablet per day;
   b. Weight > 50 kg: Both of the following (i and ii):
      i. 800 mg per day;
      ii. 2 tablets per day.

Approval duration: 12 months

C. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND

criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. All Indications in Section I (must meet all)**:**

1. Member meets one of the following (a or b):
   a. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
   b. Member is currently receiving medication and is enrolled in a state and product with continuity of care regulations (*refer to state specific addendums for CC.PHARM.03A and CC.PHARM.03B)*;
2. Member is responding positively to therapy as evidenced by one of the following (a or b):
   a. Decrease in UPCR from baseline;
   b. Reduction of proteinuria as evidence by a lower total urine protein per day from baseline;
3. Filspari is not prescribed concurrently with RAAS inhibitors, endothelin receptor antagonists (ERAs), or aliskiren;
4. If request is for a dose increase, new dose does not exceed one of the following (a or b):
   a. IgAN: Both of the following (i and ii)
      i. 400 mg per day;
      ii. 1 tablet per day;
   b. FSGS: One of the following (i or ii):
      i. Weight ≤ 50 kg: Both of the following (1 and 2):
         1. 400 mg per day;
         2. 1 tablet per day;
      ii. Weight > 50 kg: Both of the following (1 and 2):
         1. 800 mg per day;
         2. 2 tablets per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one of the following policies (a or b):
   a. For drugs on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the no coverage criteria policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.33 for health insurance marketplace/ICHRA, and CP.PMN.255 for Medicaid; or
   b. For drugs NOT on the formulary (commercial, health insurance marketplace/ICHRA) or PDL (Medicaid), the non-formulary policy for the relevant line of business: CP.CPA.190 for commercial, HIM.PA.103 for health insurance marketplace/ICHRA, and CP.PMN.16 for Medicaid; or

2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy for the relevant line of business: CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – CP.CPA.09 for commercial, HIM.PA.154 for health insurance marketplace/ICHRA, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ACEI: angiotensin-converting-enzyme inhibitor
ARB: angiotensin receptor blocker
eGFR: estimated glomerular filtration rate
ERA: endothelin receptor antagonist
FDA: Food and Drug Administration
FSGS: focal segmental glomerulosclerosis
IgAN: immunoglobulin A nephropathy
RAAS: renin-angiotensin-aldosterone system
UPCR: urine protein-to-creatinine ratio

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Maximum Dose
RAAS inhibitors	
Angiotensin-converting enzyme (ACE) inhibitors (e.g., benazepril, captopril, enalapril, lisinopril, quinapril)	Varies
Angiotensin-receptor blockers (ARB) (e.g., candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan)	Varies
SGLT2 Inhibitors	
dapagliflozin (Farxiga®)	10 mg/day
Jardiance® (empagliflozin)	10 mg/day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): pregnancy; coadministration with ARBs, ERAs, or aliskiren
- Boxed warning(s): hepatotoxicity and embryo-fetal toxicity

Appendix D: General Information

- The 2025 Kidney Disease Improving Global Outcomes (KDIGO) guideline recommends initial therapy with a RAAS inhibitor (ACEI or ARB) for all patients, except patients with contraindications such as low blood pressure, bilateral renal artery stenosis, or hyperkalemia, especially due to advanced chronic kidney disease (CKD).

- The 2025 KDIGO guideline recommends initial therapy with an SGLT2 inhibitor, for patients with proteinuria > 0.5 g per day, regardless of whether the patient has hypertension.
- Patients with IgAN who are considered high risk for progressive CKD despite maximum supportive care (defined as blood pressure control, reduction of proteinuria, and lifestyle modifications) may consider treatment with corticosteroids or immunosuppressive drugs; however, there is current uncertainty over the safety and efficacy of existing immunosuppressive treatment choices. For all patients in whom immunosuppression is being considered, a detailed discussion of the risks and benefits of each drug should be undertaken with the patient recognizing that adverse treatment effects are more likely in patients with eGFR < 50 mL/min/1.73 m^2.
- Filspari is only available through a restricted distribution program called the Filspari Risk Evaluation and Mitigation Strategies (REMS).
- Nephrotic syndrome defined as proteinuria > 3.5 g/d (adults) or UPCR > 2 g/g (pediatric patients), serum albumin < 3 g/dL, and edema at baseline.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
IgAN	Initial treatment: 200 mg PO QD Maintenance: After 14 days, increase to recommended dose of 400 mg PO QD	400 mg/day
FSGS	• Weight > 50 kg: 400 mg PO QD, then after 14 days increase to 800 mg PO QD, as tolerated • Weight ≤ 50 kg: 200 mg PO daily, then after 14 days increase to 400 mg PO Q, as tolerated	800 mg/day

VI. Product Availability

Tablets: 200 mg, 400 mg

VII. References

1. Filspari Prescribing Information. San Diego, CA: Travere Therapeutics, Inc.; April 2026. Available at: https://www.filspari.com. Accessed May 7, 2026.
2. Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int. 2021 Oct;100(4S):S1-S276. doi: 10.1016/j.kint.2021.05.021.
3. Kidney Disease: Improving Global Outcomes (KDIGO) 2025 Clinical practice guideline for the management of immunoglobulin A nephropathy (IgAN) and immunoglobulin A vasculitis (IgAV). Kidney International (2025)108(Suppl 4S), S1–S71. Available at: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf.
4. Heerspink HJL, Rovin BH, Komers R, et al. Association between complete proteinuria remission and kidney function in the phase 3 PROTECT Trial of sparsentan in IgA nephropathy. *Clin J Am Soc Nephrol.* 2026 Apr 1;21(4):578-592. doi: 10.2215/CJN.0000000961.

5. Rovin BH, Barratt J, Heerspink HJL, et al.; DUPRO steering committee and PROTECT Investigators. 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 Dec 2;402(10417):2077-2090.
6. Yee J, Gong W, Inrig J, et al. Antiproteinuric effect of sparsentan in patients with genetic-associated FSGS enrolled in the DUPLEX trial. *Clin J Am Soc Nephrol*. 2026 Apr 1;21(4):605-614. doi: 10.2215/CJN.0000000948.
7. Rheault MN, Alpers CE, Barratt J, et al; DUPRO steering committee and DUPLEX investigators. Sparsentan versus irbesartan in focal segmental glomerulosclerosis. *N Engl J Med*. 2023 Dec 28;389(26):2436-2445. doi: 10.1056/NEJMoa2308550.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	03.02.23	05.23
2Q 2024 annual review: for Appendix D, added Filspari REMS information; references reviewed and updated.	01.12.24	05.24
RT4: updated FDA Approved Indication section to reflect conversion to full approval and expanded indication.	09.11.24	
2Q 2025 annual review: added to continuation of therapy requirement that Filspari is not prescribed concurrently with RAAS inhibitors, endothelin receptor antagonists (ERAs), or aliskiren; references reviewed and updated.	01.24.25	05.25
Added step therapy bypass for IL HIM per IL HB 5395.	07.14.25	
2Q 2026 annual review: revised criterion for proteinuria ≥ 0.5 g/day per updated KDIGO 2025 guidance; references reviewed and updated. Added ICHRA line of business.	03.26.26	05.26
3Q 2026 annual review: added redirection to SGLT2i per KDIGO guideline; extended initial approval duration from 6 months to 12 months for this maintenance medication for a chronic condition; RT4: added criteria for newly approved FSGS indication; references reviewed and updated.	05.07.26	08.26

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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Note:
For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

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