

**Policy and Procedure**

<b>PHARMACY PRIOR AUTHORIZATION POLICY AND CRITERIA ORPTCGEN009.0225</b>	<b>GENITOURINARY PRODUCTS FILSPARI® (sparsentan tablet)</b>
<b>Effective Date: 4/1/2025</b>	<b>Review/Revised Date:</b> 01/24, 12/24, 01/25 (snm)
<b>Original Effective Date: 10/23</b>	<b>P&amp;T Committee Meeting Date:</b> 08/23, 02/24, 12/24, 02/25
<b>Approved by:</b> Oregon Region Pharmacy and Therapeutics Committee	

**SCOPE:**

Providence Health Plan and Providence Health Assurance as applicable (referred to individually as “Company” and collectively as “Companies”).

**APPLIES TO:**

Commercial  
Medicaid

**POLICY CRITERIA:****COVERED USES:**

All Food and Drug Administration (FDA)-Approved Indications

**REQUIRED MEDICAL INFORMATION:**

For initial authorization, all the following criteria must be met:

1. Diagnosis of primary immunoglobulin A nephropathy (IgAN), confirmed by biopsy
2. Patient has been receiving a stable dose of an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blockers (ARB), at a maximally tolerated dose, with statement that ACE or ARB will be discontinued before sparsentan therapy is initiated
3. Patient is at high risk of disease progression, defined as meeting one of the following criteria (a or b):
  - a. Proteinuria of more than 1.0 g/day; OR
  - b. Urine protein-to-creatinine ratio of 1.5 g/g or more
4. eGFR greater than or equal to 30 mL/min<sup>1.73m<sup>2</sup></sup>

Reauthorization: Documentation of positive response to therapy defined as improvement in proteinuria.

**EXCLUSION CRITERIA:**

- Concurrent therapy with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren

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**AGE RESTRICTIONS:**

May be approved for patients aged 18 years and older.

**PRESCRIBER RESTRICTIONS:**

Must be prescribed by, or in consultation with, a nephrologist.

**COVERAGE DURATION:**

Initial authorization and reauthorization will be approved for one year.

**QUANTITY LIMIT:**

Filspari 200mg: 60 tablets per 30 days

Filspari 400mg: 30 tablets per 30 days

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*Requests for indications that were approved by the FDA within the previous six (6) months may not have been reviewed by the health plan for safety and effectiveness and inclusion on this policy document. These requests will be reviewed using the New Drug and or Indication Awaiting P&T Review; Prior Authorization Request ORPTCOPS047.*

*Requests for a non-FDA approved (off-label) indication requires the proposed indication be listed in either the American Hospital Formulary System (AHFS), Drugdex, or the National Comprehensive Cancer Network (NCCN) and is considered subject to evaluation of the prescriber's medical rationale, formulary alternatives, the available published evidence-based research and whether the proposed use is determined to be experimental/investigational.*

*Coverage for Medicaid is limited to a condition that has been designated a covered line item number by the Oregon Health Services Commission listed on the Prioritized List of Health Care Services.*

*Coverage decisions are made on the basis of individualized determinations of medical necessity and the experimental or investigational character of the treatment in the individual case.*

**INTRODUCTION:**

Sparsentan is the second FDA approved medication for adults with IgAN at risk of rapid disease progression (Tarpeyo® being the first FDA approved medication).

**FDA APPROVED INDICATIONS:**

Indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.

**POSITION STATEMENT:**

- Primary IgAN impairs the kidney's ability to filter, causing blood and protein to leak into the urine. Patients will usually present with red-colored urine (hematuria), flank pain, swelling in the ankles, and high blood pressure. After living with IgAN for greater than or equal to 10 years, up to 40% of patients will

develop end state renal disease (ESRD), requiring dialysis or renal transplant. Therefore, the goal in treating IgAN is to prevent or delay progression to ESRD.<sup>4</sup>

- IgAN is a rare disease but is the most common primary glomerular disease worldwide (incidence estimated at 2 to 10 per 100,000). IgAN can present at any age but is most commonly diagnosed in patients in their 20s and 30s. Diagnosis is made by a kidney biopsy and is usually performed once a patient has persistent proteinuria.<sup>4</sup>
- Other treatments approved for IgAN include budesonide delayed-release capsule (Tarpeyo®) and iptacopan capsule (Fabhalta®). Tarpeyo® is a corticosteroid 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) greater than or equal to 1.5 g/g. Fabhalta® is an oral factor B inhibitor of the alternative complement pathway 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)  $\geq 1.5$  g/g.
- The approval of sparsentan was based on the results from one randomized, double-blind, active-control, unpublished trial (PROTECT trial) that demonstrated that sparsentan had statistically significant relative change from baseline in urine protein-to-creatinine ratio (UPCR) at week 36 when compared to irbesartan (-45% [95% CI, -51% to -38%] in the sparsentan group and -15% [95% CI, -24% to -4%] in the irbesartan group, with a p-value of  $<0.0001$ ).<sup>1,5</sup>
  - Primary endpoint was the relative change from baseline in urine protein-to-creatinine ratio (UPCR) at week 36.
  - Key study inclusion criteria included:
    - Biopsy-proven primary IgAN
    - Proteinuria equal to or greater than 1 g/day at screening
    - eGFR of equal to or greater than 30 mL/min/1.73m<sup>2</sup> at screening
    - Currently on stable dose of ACEI and/or ARB therapy, for at least 12 weeks prior to screening (maximum tolerated dose and at least one-half of the maximum labeled dose)
  - Key study exclusion criteria included:
    - IgAN secondary to another condition
    - Presence of cellular glomerular crescents in  $>25\%$  of glomeruli on renal biopsy (if biopsy available within 6 months of screening)
    - CKD in addition to IgAN
    - Treatment of systemic immunosuppressive medications (including corticosteroids) for  $>2$  weeks within three months of screening
    - Jaundice, hepatitis, or known hepatobiliary disease or elevations of transaminases (ALT/AST)  $>2$  times ULN at screening
    - Potassium greater than 5.5 mEq/L (5.5 mmol/L) at screening

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- History of serious side effect or allergic response to any angiotensin II antagonist or endothelin receptor antagonist, including sparsentan or irbesartan, or has a hypersensitivity to any of the excipients in the study medications
- Contraindications include: pregnancy, coadministration with angiotensin receptor blockers, endothelin receptor antagonists, or aliskiren
- Warnings and precautions include: hepatotoxicity, embryo-fetal toxicity, hypotension, acute kidney injury, hyperkalemia, and fluid retention
- Filspari REMS: For all patients, only available only through a restricted program under a REMS called the FILSPARI REMS because of the risk of hepatotoxicity and embryo-fetal toxicity
- The Kidney Disease: Improving Global Outcomes (KDIGO) 2021 Clinical Practice Guidelines recommend initial therapy with an ACE inhibitor or ARB for patients with proteinuria >0.5 g per day, regardless of whether or not the patient has hypertension. Clinical trials supporting the use of ACE inhibitors and ARBs are limited in IgAN, so their use is primarily based on their mechanism of slowing the rate of chronic kidney disease (CKD) progression. At least 50% of IgAN patients will not reach disease remission with an ACE inhibitor or ARB alone.<sup>6</sup> Kidney Diseases: Improving Global Outcomes (KDIGO) clinical practice DRAFT guidelines for the management of IgAN and immunoglobulin A vasculitis (2024) recommend sparsentan for patients who are at risk of progressive kidney function loss with IgAN.<sup>7</sup>

**REFERENCE/RESOURCES:**

1. Filspari® Package insert. Kansas City, MO. Catalent. September 2024.
2. Filspari® In: DRUGDEX® System [Internet database]. Greenwood Village, Colo: Thomson Reuters (Healthcare) Inc. Updated periodically. Accessed January 2, 2025.
3. Filspari® In: Lexi-Drugs Online [Internet database]. Hudson, OH: Lexi-Comp, Inc. Updated periodically. Accessed January 2, 2025.
4. Filspari (sparsentan) tablet Prime Therapeutics Monograph. Updated on March 1, 2023.
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 Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. *Kidney Int* 2021; 100:S1.

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7. Kidney Diseases: Improving Global Outcomes (KDIGO) 2024 clinical practice guidelines for the management of immunoglobulin A nephropathy (IgAN) and immunoglobulin A vasculitis (IgAV). Draft published online ahead of print. Available at: <https://kdigo.org/wpcontent/uploads/2024/08/KDIGO-2024-IgAN-IgAV-Guideline-Public-Review-Draft.pdf>. Accessed on January 12, 2025.
8. The Filspari™ REMS (Risk Evaluation and Mitigation Strategy). Available at: <https://filsparirems.com/#Main>. Accessed on: January 12, 2025.