COMMON GROUND
HEALTHCARE COOPERATIVE

# PHARMACY POLICY STATEMENT
## Common Ground Healthcare Cooperative (CGHC)

| DRUG NAME | Filspari (sparsentan) |
|---|---|
| BILLING CODE | Must use valid NDC |
| BENEFIT TYPE | Pharmacy |
| STATUS | Prior Authorization Required |

Filspari, approved by the FDA in 2023, is an endothelin and angiotensin II receptor antagonist 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) ≥1.5 g/g. This indication is approved under accelerated approval based on reduction of proteinuria demonstrated by interim results of the ongoing phase 3 PROTECT clinical trial. It has not yet been established if it slows kidney function decline. Continued approval may be contingent upon verification and description of clinical benefit in a confirmatory trial. It is only available through a REMS program due to risks of hepatotoxicity and teratogenicity.
IgA nephropathy is the most common primary glomerular disease. It is an autoimmune condition caused by deposits of immunoglobulin A (IgA) in the kidney, leading to hematuria, proteinuria, and nephropathy (kidney disease) as the kidneys become unable to filter. This can slowly progress to end stage renal disease (ESRD) requiring dialysis or kidney transplant. ACE inhibitors or angiotensin receptor blockers (ARBs) are used to slow the progression of kidney disease.

Filspari (sparsentan) will be considered for coverage when the following criteria are met:

### Primary Immunoglobulin A Nephropathy (IgAN)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has a diagnosis of IgA nephropathy confirmed by a kidney biopsy; AND
4. Chart notes must indicate risk of rapid disease progression per documentation of UPCR 1.5 g/g or greater; AND
5. Member has been stable on the max tolerated dose of an ACEi or ARB for at least 3 months; AND
6. Member's eGFR is at least 30 mL/min/1.73m$^2$; AND
7. Filspari is NOT being prescribed with any renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), or aliskiren; AND
8. Baseline liver function testing has been or will be completed prior to initiation.
9. **Dosage allowed/Quantity limit:** Initiate with 200 mg orally once a day. After 14 days, increase to the recommended dose of 400 mg once daily, as tolerated. (QL: 30 tablets per 30 days).

***If all the above requirements are met, the medication will be approved for 9 months.***

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For **reauthorization**:
1. Chart notes must show improved UPCR level compared to baseline, per lab results.

***If all the above requirements are met, the medication will be approved for an additional 12 months.***

## CareSource considers Filspari (sparsentan) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

| DATE | ACTION/DESCRIPTION |
|---|---|
| **03/31/2023** | New policy for Filspari created. |

References:


1. Filspari. [prescribing information]. Travere Therapeutics, Inc.; 2023.
2. A Study of the Effect and Safety of Sparsentan in the Treatment of Patients With IgA Nephropathy (PROTECT). ClinicalTrials.gov Identifier: NCT03762850. Updated February 2, 2023. Accessed March 31, 2023. https://clinicaltrials.gov/ct2/show/NCT03762850
3. 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(4S):S1-S276. doi:10.1016/j.kint.2021.05.021


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Revised date: 03/31/2023