

# PHARMACY POLICY STATEMENT

## Marketplace

<b>DRUG NAME</b>	<b>Filspari (sparsentan)</b>
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)  $\geq 1.5$  mg/g. 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 transplantation.

**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]. Travele 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-