HAP CareSource™

PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Filspari (sparsentan)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Filspari, approved by the FDA in 2023, is an endothelin and angiotensin II receptor antagonist indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. It is only available through a REMS program due to risks of hepatotoxicity and teratogenicity. Filspari was originally granted accelerated approval to reduce proteinuria in those at risk of rapid progression.
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 primary IgA nephropathy confirmed by renal biopsy; AND
4. Chart notes indicate risk of disease progression per documentation of proteinuria 1g/day or greater despite max tolerated dose of an ACEi or ARB for at least 3 months; AND
5. Member's eGFR is at least 30 mL/min/1.73m^2; AND
6. Filspari is NOT being prescribed with any renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), or aliskiren; AND
7. Baseline liver function testing has been or will be completed prior to initiation.
8. **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.

For **reauthorization**:
1. Chart notes must show improved proteinuria or slowed rate of eGFR decline compared to baseline.

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

HAP 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.
09/09/2024	Drug was converted from accelerated to traditional FDA approval. Changed UPCR 1.5 g/g or greater to proteinuria of 1g/day or greater and clarified that this is despite at least 3 mo of ACEi or ARB (KDIGO 2021). Removed “rapid” from disease progression (per label update). Specified “primary” IgAN (label). Added slowing of GFR decline to renewal section (per confirmatory clinical trial data).

References:

1. Filspari. [prescribing information]. Travere Therapeutics, Inc.; 2024.
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

Effective date: 04/01/2025
Revised date: 09/09/2024