

# Specialty Guideline Management

## Filspari

### Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Filspari	sparsentan

### Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

#### FDA-approved Indications<sup>1</sup>

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

All other indications are considered experimental/investigational and not medically necessary.

### Documentation

Submission of the following information is necessary to initiate the prior authorization review:

- Initial requests:
  - Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).

- Laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 gram per day (g/day) or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 grams per gram (g/g).
- Continuation requests:
  - Laboratory report and/or chart note(s) indicating the member has decreased levels of proteinuria or UPCR from baseline.

## Coverage Criteria

### Primary Immunoglobulin A Nephropathy (IgAN)<sup>1-3</sup>

Authorization of 12 months may be granted when all of the following criteria are met:

- Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.
- Member has either of the following:
  - Proteinuria greater than or equal to 1 g/day;
  - UPCR greater than or equal to 0.8 g/g
- Member has received a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor blocker [ARB]) for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to RAS inhibitors.

## Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in all members (including new members) who are currently receiving the requested medication and who are experiencing benefit from therapy as evidenced by either of the following:

- Decreased levels of proteinuria from baseline.
- Decrease in UPCR from baseline.

## References

1. Filspari [package insert]. San Diego: Trave Therapeutics, Inc.; September 2024.
2. ClinicalTrials.gov. National Library of Medicine (US). Identifier NCT03762850 A Study of the Effect and Safety of Sparsentan in the Treatment of Patients With IgA Nephropathy (PROTECT). September 6, 2023. Available from: <https://clinicaltrials.gov/ct2/show/study/NCT03762850>.

Reference number(s)
5791-A

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 Oct; 100 (4S): S1-S276. doi: 10.1016/j.kint.2021.05.021.