

Filspari (sparsentan tablets)

POLICY

I. 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

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

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

II. CRITERIA FOR INITIAL APPROVAL

Primary immunoglobulin A nephropathy (IgAN)

Authorization of 6 months may be granted when all of the following criteria are met:

- A. The medication must be prescribed by or in consultation with a nephrologist.
- B. Documentation that member has a kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
- C. Documentation with laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 g/day or UPCR greater than or equal to 0.8 g/g based on a 24-hour urine collection.
- D. Documentation that member's eGFR ≥ 30 mL/min/1.73 m² and < 90 mL/min/1.73 m².
- E. 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.
- F. Member is not using medication in combination with an ACE inhibitor, ARB, endothelin receptor antagonist (ERA), aliskiren, Tarpeyo, or Fabhalta.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when all of the following are met:

- A. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
- B. Documentation with laboratory report and/or chart note(s) indicating the member is experiencing benefit from therapy as evidenced by either of the following:
 - a. Decreased levels of proteinuria from baseline on a 24-hour urine collection
 - b. Decrease in UPCR from baseline based on a 24-hour urine collection
- C. Documentation that member's eGFR remains ≥ 30 mL/min/1.73 m² and < 90 mL/min/1.73 m².

Effective Date: 10/1/2023
Reviewed: 7/23, 5/24, 1/25
Pharmacy Scope: Medicaid

IV. QUANTITY LIMIT

Filspari 200mg and 400mg tablets have a quantity limit of 1 tablet per day.

V. REFERENCES

1. Filspari [package insert]. San Diego: Travele Therapeutics, Inc.; September 2024.
2. ClinicalTrial.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). February 3, 2023. Available from: <https://clinicaltrials.gov/ct2/show/study/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 Oct; 100 (4S): S1-S276. doi: 10.1016/j.kint.2021.05.021.