Effective Date: 10/1/2023
Reviewed: 7/23
Pharmacy Scope: Medicaid

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 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.

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

II. DOCUMENTATION

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

A. Initial requests:
   1. Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
   2. Laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 g/day or baseline UPCR greater than or equal to 1.5 g/g based on a 24-hour urine collection.

B. Continuation requests:
   1. Laboratory report and/or chart note(s) indicating the member has decreased levels of proteinuria or UPCR from baseline based on a 24-hour urine collection.

III. 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. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.
C. Member has proteinuria greater than or equal to 1 g/day or UPCR greater than or equal to 1.5 g/g based on a 24-hour urine collection.
D. Member's eGFR ≥30 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 or Tarpeyo.

IV. 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:

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.

V. QUANTITY LIMIT

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

VI. REFERENCES

1. Filspari [package insert]. San Diego: Travere Therapeutics, Inc.; February 2023.
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.