Effective Date: 10/1/2023
Reviewed: 7/23, 5/24, 1/25, 8/25, 2/26 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 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. The member is 18 years of age or older.
C. Documentation that member has a kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
D. Documentation with laboratory report and/or chart note(s) within the previous 3 months indicating the member has proteinuria greater than or equal to 0.5 g/day or UPCR greater than or equal to 0.8 g/g based on a 24-hour urine collection.
E. Documentation that member's eGFR ≥30 mL/min/1.73 m2 and < 90 mL/min/1.73 m^2.
F. 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.
G. Member is receiving a stable dose of maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to SGLT2 inhibitors.
H. Member has experienced a documented inadequate response from a 30-day trial, intolerance, or contraindication to an oral glucocorticoid (e.g., prednisone).
I. Patient is not currently receiving dialysis and has not undergone kidney transplant.
J. Member is not using medication in combination with an ACE inhibitor, ARB, endothelin receptor antagonist (ERA), aliskiren, Vanrafia, Voyxact 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 recent 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 m^2.
D. Member is not using medication in combination with an ACE inhibitor, ARB, endothelin receptor antagonist (ERA), aliskiren, Vanrafia , Voyxact or Fabhalta.

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: Travere 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.