UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 2301-1
Program	Prior Authorization/Medical Necessity
Medication	Filspari™ (sparsentan)
P&T Approval Date	4/2023
Effective Date	7/1/2023; Oxford only: 7/1/2023

1. Background:

Filspari (sparsentan) 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.

This indication is approved under accelerated approval based on a reduction in proteinuria. It has not been established whether Filspari slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Filspari** will be approved based on **all** of the following:

   a. Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

   -AND-

   b. Patient is at risk of rapid disease progression [e.g., generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g, or by other criteria such as clinical risk scoring using the International IgAN Prediction Tool]

   -AND-

   c. Used to reduce proteinuria

   -AND-

   d. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m2

   -AND-

   e. **Both** of the following:

      1) Patient is on a maximized stable dose with **one** of the following prior to initiating therapy:

a) maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
b) maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

-AND-

2) Use of renin-angiotensin-aldosterone system (RAAS) inhibitors (e.g., ACE inhibitors, ARBs), endothelin receptor antagonists [(ERAs) e.g., Letairis, Opsumit, Tracleer)], and Tekturna will be discontinued prior to initiating treatment

-AND-

g. History of failure, contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone)

-AND-

f. Prescribed by or in consultation with a nephrologist

Authorization will be issued for 12 months

B. Reauthorization

1. **Filspari** will be approved based on the following:

a. Documentation of positive clinical response demonstrated by a reduction in proteinuria

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Filspari [package insert]. San Diego, CA: Traverse Therapeutics, Inc; February 2023.
2. KDIGO 2021 Glomerular Diseases Guideline. October 2021; 100 (4S).

Program	Prior Authorization/Medical Necessity – Filspari
Change Control	
Date	Change
4/2023	New program