MEDICAL MUTUAL®

Drug Policy

Policy:	Filspari (sparsentan)	Annual Review Date:
SD		04/20/2023
		Last Revised Date:
		04/20/2023

OVERVIEW

Filspari, an endothelin and angiotensin II receptor antagonist, 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.[1] This indication is approved under accelerated approval based on reduction of 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.

Filspari is contraindicated for use with renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), or aliskiren.[1] RAAS inhibitors, ERAs, and/or aliskiren must be discontinued prior to initiation of Filspari.

POLICY STATEMENT

This policy involves the use of Filspari. Prior authorization is recommended for pharmacy benefit coverage of Filspari. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Filspari as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Filspari be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Filspari is recommended in those who meet the following criteria:

1. **Primary Immunoglobulin A Nephropathy, Initial Therapy**
   Criteria. *Patient must meet the following criteria*
   - **A.** Patient is ≥ 18 years of age; AND
   - **B.** The diagnosis has been confirmed by biopsy; AND
   - **C.** Patient is at high risk of disease progression, defined by meeting the following criteria (a and b):

a. Patient meets ONE of the following (i or ii):
  i. Proteinuria > 1.0 g/day; OR
  ii. Urine protein-to-creatinine ratio ≥ 1.5 g/g; AND
b. Patient has received the maximum or maximally tolerated dose of ONE of the following for ≥ 12 weeks prior to starting Filspari (i or ii):
  i. Angiotensin converting enzyme inhibitor; OR
  ii. Angiotensin receptor blocker; AND

D. Patient has received ≥ 3 months of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification, according to the prescriber; AND
E. Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
F. The medication will not be used in combination with any renin-angiotensin-aldosterone antagonists (e.g., angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists, or aliskiren; AND
Note: Examples of angiotensin converting enzyme inhibitors include but are not limited to lisinopril, fosinopril, enalapril, benazepril. Examples of angiotensin receptor blockers include but are not limited to irbesartan, losartan, candesartan, valsartan.
G. The medication is prescribed by or in consultation with a nephrologist

2. Primary Immunoglobulin A Nephropathy, Patient is Currently Receiving Filspari
Criteria. *Patient must meet the following criteria*

A. Patient is ≥ 18 years of age; AND
B. The diagnosis has been confirmed by biopsy; AND
C. Patient has had a response to Filspari, according to the prescriber; AND
D. Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
E. The medication is not being used in combination with any renin-angiotensin-aldosterone antagonists (e.g. angiotensin converting enzyme inhibitors or angiotensin receptor blockers), endothelin receptor antagonists, or aliskiren; AND
Note: Examples of angiotensin converting enzyme inhibitors include but are not limited to lisinopril, fosinopril, enalapril, benazepril. Examples of angiotensin receptor blockers include but are not limited to irbesartan, losartan, candesartan, valsartan.
F. The medication is prescribed by or in consultation with a nephrologist

Initial Approval/ Extended Approval.
A) *Initial Approval:* 9 months
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Filspari has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational, or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Filspari™ tablets [prescribing information]. San Diego, CA: Travere; February 2023.
2. Sparsentan for Primary IgAN, Formulary Dossier. Version 4.1 Travere. February 18, 2023
3. Kidney Diseases: Improving Global Outcomes (KDIGO) 2021 clinical practice guidelines for the management of glomerular diseases. *Kidney Int.* 2021;100:S1-S276. Available at: https://www.kidney-international.org/action/showPdf?pii=S0085-2538%2821%2900562-7. Accessed on February 20, 2023.
4. The Filspari™ REMS (Risk Evaluation and Mitigation Strategy). Available at: https://filsparirems.com/#Main. Accessed on: February 20, 2023.