AETNA BETTER HEALTH® Coverage Policy/Guideline			
Name:	Filspari	Page:	1 of 2
Effective Date:	4/7/2024	Last Review Date:	4/2024
Applies to:	☒Illinois ☒Maryland ☐Michigan	☐Florida ☒Florida Kids ☒Virginia	☒New Jersey ☒Pennsylvania Kids

Intent:

The intent of this policy/guideline is to provide information to the prescribing practitioner outlining the coverage criteria for Filspari under the patient's prescription drug benefit.

Description:

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.

Applicable Drug List:

Filspari

Policy/Guideline:

I. DOCUMENTATION

A. Initial requests:
   a. Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
   b. 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 0.8 g/g based on a 24-hour urine collection.

B. Continuation requests:

C. Laboratory report and/or chart notes indicating the member has decreased levels of proteinuria or urine protein-to-creatinine ratio (UPCR) from baseline based on a 24-hour urine collection.

II. CRITERIA FOR INITIAL APPROVAL

Primary immunoglobulin A nephropathy (IgAN)

Authorization may be granted when ALL of the following criteria are met:

A. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.

B. Proteinuria is greater than or equal to 1 g/day or UPCR is greater than or equal to 0.8 g/g based on a 24-hour urine collection.
C. 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.
D. Member has experienced an intolerance to oral glucocorticoid (e.g., prednisone).

III. CRITERIA FOR CONTINUATION OF THERAPY

Authorization may be granted 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.

Approval Duration and Quantity Restrictions:

Initial Approval: 10 months

Renewal Approval: 12 months

Quantity Level Limit: Reference Formulary for drug specific quantity level limits

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). September 6, 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.