SmartPA Criteria Proposal

Drug/Drug Class:	Filspari Clinical Edit
First Implementation Date:	November 2, 2023
Revised Date:	TBD
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☐Existing Criteria ☐Revision of Existing Criteria ☒New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of Filspari™ (sparsentan).

Why Issue Selected: On February 17, 2023, the U.S. Food and Drug Administration (FDA) approved Filspari™ (sparsentan), the first and only non-immunosuppressive therapy approved to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk of rapid disease progression.

IgAN is the most common primary glomerular disease worldwide with an estimated incidence of 2 to 10 per 100,000 people. The National Kidney Foundation estimates there are 60,000 patients with IgAN in the United States. IgAN is an autoimmune renal disease in which immunoglobulin A (IgA) accrues and attacks the glomeruli, causing impairment in kidney function. This can lead to spillage of blood and protein into the urine. Up to 40% of patients living with IgAN for at least 10 years will develop end-stage renal disease (ESRD), which requires dialysis and occasionally renal transplant. The main treatment goal in IgAN is preventing or delaying ESRD progression. Patients with a urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g may be at risk for rapid disease progression.

Filspari is an oral, once-daily, novel dual endothelin angiotensin receptor antagonist (DEARA) that inhibits both endothelin receptor type A (ETAR) and angiotensin II receptor type 1 (AT1R). This mechanism has been shown to significantly reduce proteinuria in patients with IgAN. Due its potential to cause liver abnormalities and fetal toxicity, the FDA has required a Risk Evaluation and Mitigation Strategy (REMS) program for the monitoring of those on Filspari.

Due to the high cost and specific approved indication, MO HealthNet will impose clinical criteria to ensure appropriate utilization of Filspari.

Program-Specific Information:

Drug	Cost per tablet (WAC)	Cost per month (WAC)	Cost per year (WAC)
FILSPARI 200 MG TABLET	$330	$10,038	$120,450
FILSPARI 400 MG TABLET			

Type of Criteria: ☐ **Increased risk of ADE** ☐ **Preferred Drug List**
☒ **Appropriate Indications** ☒ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Filspari™ (sparsentan).
- Age range: All appropriate MO HealthNet participants aged 18 years and older

Approval Criteria

Initial Therapy:

- Prescribed by or in consultation with an appropriate specialist in the treated disease state **AND**
- Participant is ≥ 18 years of age **AND**
- Documented diagnosis of IgAN verified by kidney biopsy **AND**
- UPCR ≥ 1.5 **AND**
- eGFR ≥ 30 mL/min/1.73 m^2 **AND**
- Participant is currently not pregnant **AND**
- Documented therapeutic trial of an ACEI or ARB at a maximally tolerated dose for at least 6 months of therapy
- Initial approval is for 3 months

Continuation of Therapy:

- Documentation of clinical benefit of therapy (e.g., reduced UPCR from baseline)
- Continuation of approval is for 1 year

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Participant is on hemodialysis
- Participant has history of renal transplant
- Claim exceeds maximum dosing limitation for the following:

Drug Description	Generic Equivalent	Max Dosing Limitation
FILSPARI 200 MG TABLET	SPARSENTAN	1 tablet per day
FILSPARI 400 MG TABLET	SPARSENTAN	1 tablet per day

Required Documentation

Laboratory Results:	X	Progress Notes:	X
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

3 months

References

- Filspari [package insert]. San Diego, CA: Travere Therapeutic, Inc.; 2023
- Trachtman H, Nelson P, Adler S et al. DUET: A Phase 2 Study Evaluating the Efficacy and Safety of Filspari in Patients with FSGS. *J Am Soc Nephrol.* 2018 Nov;29(11):2745-2754. doi: 10.1681/ASN.2018010091. Erratum in: *J Am Soc Nephrol*. 2019 Mar;30(3):518
- Komers R, Plotkin H. Dual inhibition of renin-angiotensin-aldosterone system and endothelin-1 in treatment of chronic kidney disease. *Am J Physiol Regul Integr Comp Physiol*. 2016 May 15;310(10):R877-84. doi: 10.1152/ajpregu.00425.2015
- IPD Analytics. New Drug Review: Filspari. Accessed June 1 2023.