Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	January 26, 2024

FILSPARI ™ (sparsentan)

LENGTH OF AUTHORIZATION: 6 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; **AND**
- Biopsy-proven primary immunoglobulin A nephropathy (IgAN); **AND**
- Presence of proteinuria; **AND**
- Patient is at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) ≥ 1.5 g/g; **AND**
- Patient must have had an adequate trial of an angiotensin converting enzyme (ACE) inhibitor or angiotensin II receptor blocker (ARB) at ≥ 50% of maximum labeled dose; **AND**
- Prescriber must be certified, and patient must be enrolled in Filspari Risk Evaluation and Mitigation Strategies (REMS) program*; **AND**
- Prescriber has confirmed aminotransferases (ALT, AST) are < 3x upper limit of normal (ULN) and will measure aminotransferase levels and total bilirubin monthly for the first 12 months after initiation, or when restarting therapy following an interruption due to elevated aminotransferases, then every 3 months for the duration of treatment; **AND**
- Prescriber will monitor renal function and serum potassium regularly during treatment.

CONTINUATION OF THERAPY

- Patient met initial review criteria; **AND**
- Patient must have reduction or stabilization in proteinuria; **AND**
- Patient has not experienced any treatment-restricting adverse effects (e.g., hepatotoxicity, acute kidney injury, severe hypotension, hyperkalemia); **AND**
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at https://www.accessdata.fda.gov/scripts/cder/daf/
- Available as 200 mg and 400 mg tablets.

*Because of the risks of hepatotoxicity and birth defects, FILSPARI is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the FILSPARI REMS. Further information is available at www.filsparirems.com or 1-833-513-1325.