BlueCross BlueShield Federal Employee Program

FILSPARI
(sparsentan) tablets

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Filspari (sparsentan) is a single molecule with antagonism of the endothelin type A receptor (ET_AR) and the angiotensin II type 1 receptor (AT_1R). Filspari has high affinity for both of these receptors over the endothelin type B and angiotensin II subtype 2 receptors. Endothelin-1 and angiotensin II are thought to contribute to the pathogenesis of primary immunoglobulin A nephropathy (IgAN) via the ET_AR and AT_1R, respectively (1).

Regulatory Status

FDA-approved indication: Filspari is an endothelin and angiotensin II receptor antagonist indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression (1).

Filspari contains a boxed warning regarding hepatotoxicity and embryo-fetal toxicity. Filspari is only available through a restricted distribution program called the Filspari Risk Evaluation and Mitigation Strategies (REMS) because of these risks. Some endothelin receptor antagonists have caused elevations of aminotransferases, hepatotoxicity, and liver failure. Measure liver aminotransferases and total bilirubin prior to initiation of treatment and ALT and AST monthly for 12 months, then every 3 months during treatment. Filspari can cause major birth defects in used during pregnancy. Pregnancy testing is required before, during, and after treatment. Patients who can become pregnant must use effective contraception prior to initiation of treatment, during treatment, and for one month after (1).

Prior to initiating treatment with Filspari, discontinue use of renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren (1).

People with IgA nephropathy that is causing high blood pressure may need to take medications that lower blood pressure and can also significantly slow the progression of kidney disease. Angiotensin-converting enzyme (ACE) inhibitors and angiotensin receptor blockers (ARBs) have proven effective in slowing the progression of kidney disease (2).

Filspari also contains warnings regarding hypotension, acute kidney injury, hyperkalemia, and fluid

retention (1).

The safety and efficacy of Filspari in pediatric patients less than 18 years of age have not been established (1).

Summary

Filspari is an endothelin and angiotensin II receptor antagonist indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. Filspari contains a boxed warning regarding hepatotoxicity and embryo-fetal toxicity. Filspari is only available through a restricted distribution program called the Filspari Risk Evaluation and Mitigation Strategies (REMS) because of these risks. The safety and efficacy of Filspari in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Filspari while maintaining optimal therapeutic outcomes.

References

1. Filspari [package insert]. San Diego, CA: Travere Therapeutics, Inc.; November 2024.
2. IgA Nephropathy. National Institute of Diabetes and Digestive and Kidney Diseases. November 2015. https://www.niddk.nih.gov/health-information/kidney-disease/iga-nephropathy.