sparsentan (Filspari™)

Policy # 00847
Original Effective Date: 10/09/2023
Current Effective Date: 10/09/2023

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider sparsentan (Filspari™)‡ for the treatment of primary immunoglobulin A nephropathy to be **eligible for coverage.****

Patient Selection Criteria

Coverage eligibility for sparsentan (Filspari) will be considered when the following criteria are met:

- Initial:
    - Patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN); AND
    - Patient is ≥18 years of age; AND
    - Diagnosis has been confirmed by biopsy; AND
    - According to the prescriber, the patient has received ≥90 days of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification; AND
      *(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*
    - Patient is at high risk of disease progression, defined by meeting the following criteria:
        - Patient meets ONE of the following:
            - ❖ Proteinuria ≥1 g/day; OR
            - ❖ Urine protein to creatinine ratio ≥1.5 g/g; AND
        - Patient has been receiving the maximally tolerated dose of an angiotensin converting enzyme inhibitor (ACEi) (e.g., lisinopril, enalapril, benazepril, captopril, fosinopril, moexipril, perindopril, quinapril, ramipril, trandolapril)

or angiotensin receptor blocker (ARB) (e.g., candesartan, irbesartan, losartan, olmesartan, telmisartan, valsartan) for ≥90 days; AND
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Filspari will not be used in combination with and ACEi, ARB, endothelin receptor antagonist (ERA) or aliskiren; AND
- Patient has an estimated glomerular filtration rate (eGFR) ≥30 mL/min/1.73m^2
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met.)*

- Continuation:
  - Patient has received an initial authorization from BCBSLA for Filspari; AND
  - According to the prescribing physician, patient is continuing to derive benefit from Filspari. Examples of treatment benefits include reduction in urine protein-to-creatinine ratio from baseline or reduction in proteinuria from baseline.

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of sparsentan (Filspari) when the patient has not received at least 90 days of optimized supportive care, the patient has not been receiving the maximally tolerated dose of an ACEi or ARB for at least 90 days, or the patient has an estimated glomerular filtration rate <30 mL/min/1.73 m^2 to be **not medically necessary.****

When Services Are Considered Investigational

Coverage is not available for investigational medical treatments or procedures, drugs, devices or biological products.

Based on review of available data, the Company considers the use of sparsentan (Filspari) when the patient selection criteria are not met (except those denoted above as **not medically necessary.****) to be **investigational.***

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Background/Overview

Filspari is an endothelin type A and angiotensin II type 1 receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression. It should be administered once daily by mouth to eligible patients. It is important to note that Filspari is contraindicated in combination with renin-angiotensin-aldosterone system (RAAS) inhibitors, endothelin receptor antagonists (ERAs), and aliskiren. These agents should be discontinued prior to initiation of treatment with Filspari. Additionally, patients must be monitored for elevated aminotransferases, total bilirubin, and pregnancy (in patients who can become pregnant) as these are additional contraindications to treatment.

IgAN is the most common cause of primary glomerulonephritis in resource-abundant settings. Around 25% of patients with this condition have a slow progression to end-stage kidney disease (ESKD) within 25 years of presentation. The remaining patients enter a sustained remission or have persistent low-grade hematuria and/or proteinuria. Some of the proposed risk factors for disease progression include proteinuria above 1 g/day, hypertension, reduced eGFR, hematuria, certain histologic predictors on kidney biopsy, and modifiable factors such as obesity, hypertriglyceridemia, and smoking. The goal of treating IgAN is to prevent disease progression to ESKD by reducing proteinuria to less than 0.5 to 1 g/day and resolving microscopic hematuria. The first-line treatment options to achieve this goal are supportive care with blood pressure control, maximally tolerated renin-angiotensin system blockade, treatment with a sodium-glucose contransporter-2 (SGLT2) inhibitor, and lifestyle modification. After 3-6 months of optimized supportive care, patients at high risk (e.g., those with proteinuria $\geq$1 g/day) may require further therapy with immunosuppressive agents such as glucocorticoids to reduce risk.

FDA or Other Governmental Regulatory Approval

U.S. Food and Drug Administration (FDA)

Filspari was approved in February 2023 to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio $\geq$1.5 g/g.

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Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

The effect of Filspari on proteinuria was assessed in a randomized, double-blind, active-controlled, multicenter, global study in adults with biopsy-proven IgAN, eGFR $\geq$30 mL/min/1.73 m^2, and total urine protein $\geq$1.0g/day on a maximized stable dose of RAS inhibitor treatment that was at least 50% of maximum labeled dose. Patients with other glomerulopathies or those who had been recently treated with systemic immunosuppressants were excluded.

Patients (n=281) were randomized (1:1) to either Filspari (400 mg once daily following 200 mg once daily for 14 days) or irbesartan (300 mg once daily following 150 mg once daily for 14 days). Rescue immunosuppressive treatment could be initiated per investigator discretion during the trial, but use of SGLT2 inhibitors was prohibited.

The primary endpoint was the relative change from baseline in UPCR at Week 36. In the Filspari group (n=141), the mean UPCR decreased 45% from a baseline of 1.2 to 0.7 g/g. In the irbesartan group, the mean UPCR decreased 15% from a baseline of 1.2 to 1.0 g/g. This corresponds to a Filspari to irbesartan ratio of adjusted mean UPCR relative to baseline of 0.65 (95% CI: 0.55, 0.77).

References

1. Filspari [package insert]. Travere Therapeutics, Inc. San Diego, CA. Updated February 2023.
2. IgA Nephropathy: Treatment and Prognosis. UpToDate. Updated July 2023.

Policy History

Original Effective Date: 10/09/2023
Current Effective Date: 10/09/2023
09/07/2023 Medical Policy Committee review
09/13/2023 Medical Policy Implementation Committee approval. New policy.

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Next Scheduled Review Date: 09/2024

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally

recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.