Filspari (sparsentan)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

The intent of the Filspari (sparsentan) policy is to provide coverage consistent with product labeling, FDA guidance, standards of medical practice, evidence-based drug information, and/or published guidelines. The indications below including FDA-approved indications and compendial uses are considered covered benefits provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

Filspari (sparsentan) is an endothelin and angiotensin II receptor antagonist 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. It has not been established whether Filspari slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

POLICY

Required Documentation

Submission of the following information is necessary to initiate the prior authorization review:

1. For initial requests:
    i. Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
    ii. Laboratory report and/or chart note indicating that the member has proteinuria greater than or equal to 1 g/day based on a 24-hour urine collection.

iii. Laboratory report and/or chart note indicating that the member is at risk for disease progression with a UPCR greater than or equal to 1.5 g/g based on a 24-hour urine collection.

2. For continuation requests: Chart notes or medical record documentation supporting positive clinical response.

Prescriber Specialties

Filspari must be prescribed by or in consultation with a nephrologist.

Criteria for Initial Approval

Authorization of up to 9 months may be granted when all of the following criteria are met:

1. Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.
2. Member is 18 years of age or older.
3. Member has proteinuria greater than or equal to 1 g/day based on a 24-hour urine collection despite receiving a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitors [ACEIs] or angiotensin II receptor blockers [ARBs]) for at least 3 months.
4. Member is at risk for rapid disease progression defined by urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g based on a 24-hour urine collection.
5. Member has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73m^2.
6. The requested medication will not be used in combination with Tarpeyo (budesonide delayed release).

Continuation of Therapy

Authorization of 12 months may be granted for all members who are using the requested medication for proteinuria reduction in primary immunoglobulin A nephropathy when the following criteria are met:

1. Member has an estimated glomerular filtration rate (eGFR) greater than or equal to 30 mL/min/1.73m^2.
2. Member achieves or maintains a positive clinical response as evidenced by one of the following:
   i. Reduction in proteinuria from baseline
   ii. Reduction in UPCR from baseline

Filspari is considered **not medically necessary** for members who do not meet the criteria set forth above.

Dosing and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Quantity Limits

- Filspari 200mg, 400mg tablets – 30 tablets per 30 days

CLINICAL RATIONALE

Filspari (sparsentan) is an oral, once-daily, endothelin and angiotensin II receptor antagonist indicated for the reduction of proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression. Blockade of endothelin-1 and angiotensin II pathways has been shown to reduce proteinuria, protect podocytes, and prevent glomerulosclerosis in IgAN. Currently, initial treatment for IgAN consists of off-label use with angiotensin converting enzyme inhibitors (ACEi) or angiotensin II type 1

receptor blockers (ARB) based on their mechanism of slowing chronic kidney disease progression. Filspari (sparesentan) is the first FDA-approved non-immunosuppressant medication for IgAN.

Efficacy

The efficacy and safety of Filspari (sparsentan) were evaluated in an unpublished, randomized, double-blind, active-controlled, multicenter, global clinical trial (PROTECT) in 281 adult patients (69% male; 62% White, 35% Asian; mean age 46 years) with biopsy-proven IgAN, eGFR ≥ 30 mL/min/1.73 m2 and total urine protein ≥ 1 g/day who were on a maximized dose of renin-angiotensin system (RAS) inhibitor treatment that was at least 50% of maximum labeled dose (Filspari prescribing information, 2023). Patients were assigned in a 1:1 ratio to either Filspari (sparsentan) 400mg or irbesartan 300mg once daily. At baseline, mean eGFR was 56 mL/min/1.73 m2, 77% had a history of hypertension, 12% had a history of diabetes and 53% had hematuria. Rescue immunosuppressive treatment could be initiated per investigator discretion but use of a sodium-glucose cotransporter-2 (SGLT2) inhibitor was prohibited. The primary endpoint was relative change from baseline in urine protein creatinine ratio (UPCR) at week 36.

Patients treated with Filspari (sparsentan) had a 45% reduction in UPCR at 9 months compared with a 15% reduction for patients treated with irbesartan (treatment difference 30%, $p < 0.0001$) (Filspari prescribing information, 2023). Treatment effect on UPCR was consistent across subgroups such as age, sex, race, and baseline eGFR and proteinuria levels. Rescue immunosuppressive treatment was initiated in 1.4% and 5.7% of Filspari (sparsentan) and irbesartan patients, respectively.

Safety

Although Filspari (sparsentan) did not demonstrate severe liver toxicity in the PROTECT trial, the FDA has required a Risk Evaluation and Mitigation Strategy (REMS) program for risk of hepatotoxicity and embryo-fetal toxicity like other endothelin receptor antagonists (ERA). Other warnings include hypotension, acute kidney injury, hyperkalemia, and fluid retention. The most common adverse events associated with Filspari (sparsentan) in trials include peripheral edema (14%), hypotension (14%), dizziness (13%), hyperkalemia (13%), anemia (5%), acute kidney injury (4%), and transaminase elevations (2.5%). Due to its mechanism of action, Filspari should not be coadministered with RAS inhibitors, ERAs or aliskiren. Filspari is a CYP3A4 substrate and concomitant use with strong CYP3A4 inducers or inhibitors should be avoided.

In summary, although Filspari (sparsentan) has demonstrated efficacy in reducing proteinuria in patients with IgAN, clinical benefit has not been confirmed. It has not been established whether Filspari (sparsentan) slows kidney function decline in patients with IgAN. Since Filspari (sparsentan) received accelerated approval, continued approval is contingent upon confirmation of a clinical benefit. Results from the ongoing PROTECT trial are needed to fully assess treatment effect on eGFR slope and kidney function to confirm clinical benefit.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Filspari [package insert]. San Diego, CA: Travere Therapeutics, Inc.; February 2023.
- 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.

- A Randomized, Multicenter, Double-blind, Parallel-group, Active-control Study of the Efficacy and Safety of Sparsentan for the Treatment of Immunoglobulin A Nephropathy. clinicaltrials.gov. Published February 1, 2023.

POLICY HISTORY

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