Filspari (sparsentan) Prior Authorization with Quantity Limit Program Summary

This program applies to MN Medicaid.

The BCBS MN Step Therapy Supplement also applies to this program for Medicaid.

POLICY REVIEW CYCLE

Effective Date
10/1/2023

Date of Origin
10/1/2023

FDA APPROVED INDICATIONS AND DOSAGE

Agent(s)	FDA Indication(s)	Notes	Ref#
Filspari™ (sparsentan) Tablet	Reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g		1

See package insert for FDA prescribing information: https://dailymed.nlm.nih.gov/dailymed/index.cfm

CLINICAL RATIONALE

Immunoglobulin A Nephropathy (2,3,4)	Immunoglobulin A nephropathy (IgAN), also known as Berger's disease, is a kidney disease that occurs when IgA deposits build up in the kidneys, causing inflammation that damages the glomeruli, in turn causing the kidneys to leak blood and protein into the urine. The damage may lead to scarring of the nephrons that progresses slowly over may years. Eventually, IgAN can lead to end-stage renal disease (ESRD). IgAN cannot be reliably diagnosed with blood or urine tests and kidney biopsy is required to confirm the diagnosis. Biopsy is usually only performed if there are signs suggestive of more severe or progressive disease, such as persistent proteinuria of at least 500 mg per day or an elevated serum creatinine concentration. After a diagnosis has been established, underlying causes of secondary IgAN (e.g., liver cirrhosis, HIV, hepatitis, inflammatory bowel disease) should be considered. The primary focus of IgAN management should be optimized supportive care [e.g., blood pressure management, maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI) or angiotensin II blocker (ARB), lifestyle modification, address cardiovascular risk]. Guidelines recommend that all patients with proteinuria greater than 0.5g/dL be treated with an ACEI or ARB irrespective of whether they have hypertension. Guidelines define high risk of progression in IgAN as proteinuria greater than 0.75 – 1 g/d despite at least 90 days of optimized supportive care. It is suggested that patients who remain at high risk despite maximal supportive care be considered for a 6 month course of glucocorticoid therapy. They stress the importance of discussing treatment-emergent toxicity, particularly those who have an eGFR less than 50 mL/min/1.73 m^2. It is further noted that glucocorticoids should be given with extreme caution or avoided entirely in the following situations: • eGFR less than 30 mL/min/1.73 m^2 • Diabetes • Obesity (BMI greater than 30 kg/m^2)

	• Latent infections (e.g., viral hepatitis, tuberculosis) • Secondary disease (e.g., cirrhosis) • Active peptic ulceration • Uncontrolled psychiatric illness • Severe osteoporosis
Efficacy(1,5)	Filspari (sparsentan) is an endothelin and angiotensin II receptor antagonist. The effect of Filspari on proteinuria was assessed in a randomized, double-blind, active-controlled, multicenter, global study (PROTECT, NCT03762850) in adults with biopsy-proven IgAN, eGFR greater than or equal to 30 mL/min/1.73 m^2, and total urine protein greater than or equal to 1.0 g/day on a maximized stable dose of renin-angiotensin- system (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. Other exclusion criteria included chronic kidney disease, history of organ transplantation, with exception of corneal transplants, history of heart failure or previous hospitalization for heart failure or unexplained dyspnea, orthopnea, paroxysmal nocturnal dyspnea, ascites, and/or peripheral edema, clinically significant cerebrovascular disease or coronary artery disease within 6 months, jaundice, hepatitis, or known hepatobiliary disease or elevations of transaminases (ALT/AST) greater than 2 times upper limit of normal at screening, history of malignancy other than adequately treated basal cell or squamous cell skin cancer or cervical carcinoma within the past 2 years, hematocrit value less than 27% (0.27 V/V) or hemoglobin value less than 9 g/dL (90 g/L), and potassium greater than 5.5 mEq/L (5.5 mmol/L). Patients 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 281 patients who reached week 36 had a mean age of 46 years (range 18 to 76 years); 69% were male, 62% White, 35% Asian, and 1% Black or African American. Approximately 77% had a history of hypertension, 12% diabetes or impaired fasting glucose, and 53% hematuria. Mean (SD) baseline eGFR was 56 (24) mL/min/1.73 m^2. The primary endpoint was the relative change from baseline in urine protein to creatinine ratio (UPCR) at week 36. The mean percentage change from baseline was -45% in the Filspari arm and -15% in the irbesartan arm.
Safety(1)	Filspari (sparsentan) has a boxed warning for hepatotoxicity and embryo-fetal toxicity and is available only through a risk evaluation and mitigation strategy (REMS) program. Elevation of aminotransferases (ALT or AST) of at least 3 times the upper limit of normal (ULN) were observed in up to 2.5% of Filspari treated patients in clinical trials. Transaminases and bilirubin should be measured before initiating treatment, and monthly for the first 12 months, and then every 3 months during treatment. Filspari should be avoided in patients with elevated aminotransferases greater than 3 times ULN at baseline. Treatment with Filspari should be discontinued in patients developing aminotransferase elevations greater than 3 times ULN. Because Filspari can cause major birth defects if used by pregnant patients, pregnancy testing is required before initiation of treatment, during treatment, and one month after discontinuation of treatment with Filspari. Patients who can become pregnant must use effective contraception before the initiation of treatment, during, and for one month after the discontinuation of treatment with Filspari. Filspari is contraindicated in patients who are pregnant. Filspari should not be coadministered with ARBs, endothelin receptor antagonists (ERAs), or aliskiren.

REFERENCES

Number	Reference
1	Filspari prescribing information. Travere Therapeutics, Inc. February 2023

Number	Reference
2	IgA Nephropathy. Nation Institute of Diabetes and Digestive and Kidney Diseases. U.S. Department of Health and Human Services. https://www.niddk.nih.gov/health-information/kidney-disease/iga-nephropathy
3	Wyatt RJ, Julian BA. IgA nephropathy. *New England Journal of Medicine*. 2013;368(25):2402–2414.
4	Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. Kidney Int 2021; 100:S1.
5	https://clinicaltrials.gov/ct2/show/NCT03762850

POLICY AGENT SUMMARY PRIOR AUTHORIZATION

Target Brand Agent(s)	Target Generic Agent(s)	Strength	Targeted MSC	Available MSC	Final Age Limit	Preferred Status
Filspari	sparsentan tab	200 MG ; 400 MG	M ; N ; O ; Y	N		

POLICY AGENT SUMMARY QUANTITY LIMIT

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	QL Amount	Dose Form	Day Supply	Duration	Addtl QL Info	Allowed Exceptions	Targeted NDCs When Exclusions Exist
Filspari	sparsentan tab	200 MG	30	Tablets	30	DAYS			
Filspari	sparsentan tab	400 MG	30	Tablets	30	DAYS			

CLIENT SUMMARY – PRIOR AUTHORIZATION

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Filspari	sparsentan tab	200 MG ; 400 MG	Medicaid

CLIENT SUMMARY – QUANTITY LIMITS

Target Brand Agent Name(s)	Target Generic Agent Name(s)	Strength	Client Formulary
Filspari	sparsentan tab	200 MG	Medicaid
Filspari	sparsentan tab	400 MG	Medicaid

PRIOR AUTHORIZATION CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
	Initial Evaluation **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND** 2. ONE of the following: A. The patient has a urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g **OR** B. The patient has proteinuria greater than or equal to 1 g/day **AND** 3. The patient's eGFR is greater than or equal to 30 mL/min/1.73 m^2 **AND** 4. If the patient has an FDA approved indication, then ONE of the following: A. The patient's age is within FDA labeling for the requested indication for the requested agent **OR** B. The prescriber has provided information in support of using the requested agent for the patient's age for the requested indication **AND** 5. ONE of the following A. BOTH of the following: 1. The patient's medication history includes at least 3 months of therapy with maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II

Module	Clinical Criteria for Approval
	blocker (ARB, e.g., losartan), or a combination medication containing an ACEI or ARB as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The presciber has stated that the patient has tried at least 3 months of therapy with maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an ACEI or ARB **AND** 2. ONE of the following: A. The ACEI or ARB was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL ACEI or ARB medications **OR** B. The patient has an intolerance or hypersensitivity to an ACEI or ARB, or a combination medication containing an ACEI or ARB, that is not expected to occur with the requested agent **OR** C. The patient has an FDA labeled contraindication to ALL ACEI or ARB that is not expected to occur with the requested agent **OR** D. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR** E. The prescriber has provided documentation that ALL ACEI and ARB medications cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 6. ONE of the following: A. BOTH of the following: 1. The patient has tried and had an inadequate response after a 6 month course of glucocorticoid therapy (e.g., methylprednisolone, prednisolone, prednisone) as indicated by ONE of the following: A. Evidence of a paid claim(s) **OR** B. The presciber has stated that the patient has tried at least 3 months of therapy with maximally tolerated angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril) or angiotensin II blocker (ARB, e.g., losartan), or a combination medication containing an glucocorticoid **AND** 2. ONE of the following: A. The glucocorticoid was discontinued due to lack of effectiveness or an adverse event **OR** B. The prescriber has submitted an evidence-based and peer-reviewed clinical practice guideline supporting the use of the requested agent over ALL glucocorticoids **OR** B. The patient has an intolerance or hypersensitivity to a glucocorticoid **OR** C. The patient has an FDA labeled contraindication to ALL glucocorticoids **OR** D. The prescriber has provided information to support that glucocorticoid therapy is NOT appropriate for the patient **OR** E. The patient is currently being treated with the requested agent as indicated by ALL of the following: 1. A statement by the prescriber that the patient is currently taking the requested agent **AND** 2. A statement by the prescriber that the patient is currently receiving a positive therapeutic outcome on requested agent **AND** 3. The prescriber states that a change in therapy is expected to be ineffective or cause harm **OR**

Module	Clinical Criteria for Approval
	F. The prescriber has provided documentation that ALL glucocorticoids cannot be used due to a documented medical condition or comorbid condition that is likely to cause an adverse reaction, decrease ability of the patient to achieve or maintain reasonable functional ability in performing daily activities or cause physical or mental harm **AND** 7. The patient will NOT use the requested agent in combination with an ACEI, ARB, endothelin receptor antagonist (ERA, e.g., bosentan), or aliskiren **AND** 8. The patient does NOT have any of the following: A. IgAN secondary to another condition B. Chronic kidney disease C. History of organ transplantation, with exception of corneal transplants D. History of heart failure or previous hospitalization for heart failure or unexplained dyspnea, orthopnea, paroxysmal nocturnal dyspnea, ascites, and/or peripheral edema E. Clinically significant cerebrovascular disease or coronary artery disease within 6 months F. Jaundice, hepatitis, or known hepatobiliary disease or elevations of transaminases (ALT/AST) greater than 2 times upper limit of normal at screening G. History of malignancy other than adequately treated basal cell or squamous cell skin cancer or cervical carcinoma within the past 2 years H. Hematocrit value less than 27% (0.27 V/V) or hemoglobin value less than 9 g/dL (90 g/L) I. Potassium greater than 5.5 mEq/L (5.5 mmol/L) **AND** 9. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 10. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 9 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents. **Renewal Evaluation** **Target Agent(s)** will be approved when ALL of the following are met: 1. The patient has been previously approved for the requested agent through the plan's Prior Authorization process **AND** 2. The patient has had improvements or stabilization with the requested agent as indicated by ONE of the following: A. Decrease from baseline (prior to treatment with the requested agent) of urine protein-to-creatinine (UPCR) ratio **OR** B. Decrease from baseline (prior to treatment with the requested agent) in proteinuria **AND** 3. The patient will NOT use the requested agent in combination with an angiotensin-converting-enzyme inhibitor (ACEI, e.g., benazepril, lisinopril), angiotensin II blocker (ARB, e.g., losartan), endothelin receptor antagonist (ERA, e.g., bosentan), or aliskiren **AND** 4. The prescriber is a specialist in the area of the patient's diagnosis (e.g., nephrologist) or the prescriber has consulted with a specialist in the area of the patient's diagnosis **AND** 5. The patient does NOT have any FDA labeled contraindications to the requested agent **Length of Approval:** 12 months NOTE: If Quantity Limit program also applies, please refer to Quantity Limit documents.

QUANTITY LIMIT CLINICAL CRITERIA FOR APPROVAL

Module	Clinical Criteria for Approval
QL with PA	**Target Agent(s)** will be approved when ONE of the following is met:

Module	Clinical Criteria for Approval
	1. The requested quantity (dose) does NOT exceed the program quantity limit **OR** 2. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) does NOT exceed the maximum FDA labeled dose for the requested indication **AND** C. The requested quantity (dose) cannot be achieved with a lower quantity of a higher strength that does NOT exceed the program quantity limit **OR** 3. ALL of the following: A. The requested quantity (dose) is greater than the program quantity limit **AND** B. The requested quantity (dose) is greater than the maximum FDA labeled dose for the requested indication **AND** C. The prescriber has provided information in support of therapy with a higher dose for the requested indication **Length of Approval:** Initial, 9 months; Renewal, 12 months