BlueCross BlueShield Arizona

An Independent Licensee of the Blue Cross Blue Shield Association

PHARMACY COVERAGE GUIDELINE

FILSPARI™ (sparsentan) oral
VANRAFIA™ (atrasentan) oral
Generic Equivalent (if available)

This Pharmacy Coverage Guideline (PCG):
- Provides information about the reasons, basis, and information sources we use for coverage decisions
- Is not an opinion that a drug (collectively "Service") is clinically appropriate or inappropriate for a patient
- Is not a substitute for a provider's judgment (Provider and patient are responsible for all decisions about appropriateness of care)
- Is subject to all provisions e.g. (benefit coverage, limits, and exclusions) in the member's benefit plan; and
- Is subject to change as new information becomes available.

Scope
- This PCG applies to Commercial and/or Marketplace plans
- This PCG does not apply to the Federal Employee Program, Medicare Advantage, Medicaid or members of out-of-state Blue Cross and/or Blue Shield Plans

Instructions & Guidance
- To determine whether a member is eligible for the Service, read the entire PCG.
- This PCG is used for FDA approved indications including, but not limited to, a diagnosis and/or treatment with dosing, frequency, and duration.
- Use of a drug outside the FDA approved guidelines, refer to the appropriate Off-Label Use policy.
- The "Criteria" section outlines the factors and information we use to decide if the Service is medically necessary as defined in the Member's benefit plan.
- The "Description" section describes the Service.
- The "Definition" section defines certain words, terms or items within the policy and may include tables and charts.
- The "Resources" section lists the information and materials we considered in developing this PCG
- **We do not accept patient use of samples as evidence of an initial course of treatment, justification for continuation of therapy, or evidence of adequate trial and failure.**
- Information about medications that require prior authorization is available at www.azblue.com/pharmacy. You must fully complete the request form and provide chart notes, lab workup and any other supporting documentation. The prescribing provider must sign the form. Fax the form to BCBSAZ Pharmacy Management at (602) 864-3126 or email it to Pharmacyprecert@azblue.com.

Medical Necessity Requirements for FILSPARI (sparsentan)

Criteria for Initial Therapy:

Prescriber Qualifications
- Prescribed by a Nephrologist or Immunologist, or in consultation with one

Indication
- Primary immunoglobulin A nephropathy (IgAN) at high risk for disease progression, used to slow kidney function decline
- Focal segmental glomerulosclerosis (FSGS) **without** nephrotic syndrome, used to reduce proteinuria

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Age Requirement

- **ONE** of the following:
  - **For primary immunoglobulin A nephropathy (IgAN):** 18 years or older
  - **For focal segmental glomerulosclerosis (FSGS):** 8 years or older

Baseline Clinical Evaluation

- **For primary immunoglobulin A nephropathy (IgAN):**
  - Persistent overt proteinuria and remains high risk for rapid disease progression despite stable doses of angiotensin converting enzyme inhibitor (ACEI) and/or angiotensin receptor blocker (ARB)
  - Biopsy proven IgAN (performed at any time)
  - Proteinuria of at least 1 gram per day
  - Blood pressure controlled (systolic less than or equal to 120 mmHg and diastolic less than or equal to 70 mmHg)
- **For focal segmental glomerulosclerosis (FSGS):**
  - Biopsy proven FSGS (performed at any time) or a genetic mutation known to cause FSGS
  - Light microscopy (LM) and findings on either electron microscopy (EM) or immunofluorescence (IF) analysis supports diagnosis of FSGS
  - Does not have **ANY** of the following for nephrotic syndrome
    1. Urine protein to creatinine greater than 3.5 g/24 hours (adults) or greater than 2.0 g/g (pediatric patients less than 18 years of age)
    2. Serum albumin less than 3.0 g/dL
    3. Edema on physical exam
- **For EITHER IgAN or FSGS:**
  - Estimated glomerular filtration rate is at least 30 mL/min/1.73 m²
  - Liver aminotransferases and total bilirubin
  - Negative pregnancy test in a woman of childbearing potential
  - Woman of childbearing potential is using effective contraception
  - Enrolled in the FILSPARI REMS program

Alternative Therapies

- Failure (at least 12 weeks of a maximized stable dose that was at least one half of the maximum labeled dose), contraindication, intolerance to **ALL** the following:
  - **ONE** ACE inhibitor (e.g., lisinopril, enalapril, etc.) or ARB (e.g., losartan, irbesartan, etc.)
  - **ONE** SGLT2 inhibitor (e.g., dapagliflozin)
  - Prednisone (or methylprednisolone)

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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Safety

No concomitant use of:
- Renin angiotensin aldosterone system inhibitors (ACE inhibitors, ARBs)
- Endothelin receptor antagonists (e.g., ambrisentan, bosentan, macitentan)
- Aliskiren
- Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, etc.)
- Strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, etc.)
- Potassium sparing agents (e.g., amiloride, triamterene, spironolactone, eplerenone)

- Does not have hepatic impairment (Child Pugh A, B, C)
- Will not be used concurrently with Vanrafia (atrasentan)

Documentation Requirements

- A completed request form must be submitted including:
  - Chart notes
  - Lab results (proteinuria, eGFR, liver function tests, pregnancy test)
  - Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Nephrologist or Immunologist, or in consultation with one

Clinical Response

- **TWO** of the following:
  - Improvement in urine protein to creatinine ratio
  - Improvement in proteinuria
  - Improvement in eGFR
  - Reduced need for rescue immunosuppressive treatment

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

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Safety

- There is **NONE** of the following:
  - Elevated aminotransferases greater than three times the upper limit of normal
  - Hepatotoxicity or unresolved liver enzyme abnormalities
  - Clinically significant decrease in kidney function
  - Significant hyperkalemia despite treatment
  - Significant fluid retention
  - Hepatic impairment (Child Pugh A, B, C)
  - Estimated glomerular filtration rate is less than 30 mL/min/1.73 m²
- No concomitant use of:
  - Renin angiotensin aldosterone system inhibitors (ACE inhibitors, ARBs)
  - Endothelin receptor antagonists (e.g., ambrisentan, bosentan, macitentan)
  - Aliskiren
  - Strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, clarithromycin, etc.)
  - Strong CYP3A inducers (e.g., rifampin, rifabutin, phenobarbital, carbamazepine, phenytoin, etc.)
  - Potassium sparing agents (e.g., amiloride, triamterene, spironolactone, eplerenone)
  - Concurrent use with Vanrafia (atrasentan)

Documentation Requirements

- Chart notes
- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Medical Necessity Requirements for VANRAFIA (atrasentan)

Criteria for Initial Therapy:

Prescriber Qualifications

- Prescribed by a Nephrologist or Immunologist, or in consultation with one

Indication

- Primary immunoglobulin A nephropathy (IgAN) with persistent overt proteinuria and at high risk for rapid disease progression despite use of stable doses of angiotensin converting enzyme inhibitor (ACEI) and/or angiotensin receptor blocker (ARB)

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Generic Equivalent (if available)

Age Requirement
- 18 years or older

Baseline Clinical Evaluation
- Biopsy proven IgAN (performed at any time)
- Proteinuria of at least 1 gram per day
- Estimated glomerular filtration rate is at least 30 mL/min/1.73 m²
- Blood pressure controlled (systolic less than or equal to 120 mmHg and diastolic less than or equal to 70 mmHg)
- Liver aminotransferases and total bilirubin
- Negative pregnancy test in a woman of childbearing potential
- Woman of childbearing potential is using effective contraception
- Will be used in combination with renin angiotensin aldosterone system (RAAS) inhibitor (e.g. ACEI, ARB)

Alternative Therapies
- Failure (trial for at least three months duration), contraindication, intolerance to **ALL** of the following:
  - **ONE** angiotensin converting enzyme inhibitor (ACE inhibitor such as lisinopril, enalapril) or angiotensin receptor blocker (ARB such as losartan, irbesartan)
  - **ONE** sodium glucose co transporter 2 (SGLT2) inhibitor (e.g., dapagliflozin)
  - Prednisone (or methylprednisolone)

Brand Specific Criteria
- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety
- No concomitant use with:
  - Moderate or strong CYP3A inducers
  - OATP1B1/1B3 inhibitors (e.g., cyclosporine, protease inhibitors, clarithromycin)
  - Filspari (sparsentan)
- Does not have:
  - Severe hepatic impairment (Child Pugh C)
  - Diagnosis of heart failure
  - Previous hospitalization for heart failure
  - B type natriuretic peptide level greater than 200 pg/mL

Documentation Requirements
- A completed request form must be submitted including:
  - Chart notes

- Lab results (proteinuria, eGFR, liver function tests, pregnancy test, BNP if applicable)
- Supporting clinical documentation

Initial Therapy Criteria Approval Duration

- 6 months OR end of plan year

Criteria for Continuation of Therapy (renewal therapy):

Note: Manufacturer assistance (e.g., coupons, samples, etc.) are not considered for continuation of therapy.

Prescriber Qualification

- Continues to be seen by a Nephrologist or Immunologist, or in consultation with one

Clinical Response

- **TWO** of the following:
  - Improvement in urine protein to creatinine ratio
  - Improvement in proteinuria
  - Improvement in eGFR
  - Reduced need for rescue immunosuppressive treatment

Adherence

- Adherence to the prescribed therapy regimen has been documented

Brand Specific Criteria

- Have failure, contraindication, or intolerance with **THREE** generic equivalents (if available) for at least three months each. **Note:** Any failure, contraindication, or intolerance to the generic drugs should be reported to the FDA (see Definitions section)

Safety

- No concomitant use with:
  - Moderate or strong CYP3A inducers
  - OATP1B1/1B3 inhibitors (e.g., cyclosporine, protease inhibitors, clarithromycin)
  - Filspari (sparsentan)
- Does not have:
  - Elevated aminotransferases greater than three times the upper limit of normal
  - Hepatotoxicity or unresolved liver enzyme abnormalities
  - Significant fluid retention
  - No heart failure

Documentation Requirements

- Chart notes

- Supporting clinical documentation with evidence of improvement
- Lab values confirming safe use

Continuation Therapy Criteria Approval Duration

- 12 months OR end of plan year

Criteria for Off-Label Use Requests:

Criteria for a request for non-FDA use or indication, treatment with dosing, frequency, or duration outside the FDA-approved dosing, frequency, and duration, refer to one of the following Pharmacy Coverage Guideline:

1. Off-Label Use of Non-Cancer Medications

2. Off-Label Use of Cancer Medications

Description:

Filspari (sparsentan) is indicated to slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. Filspari (sparsentan) is also indicated to reduce proteinuria in adult and pediatric patients aged 8 years and older with focal segmental glomerulosclerosis (FSGS) **without** nephrotic syndrome.

Vanrafia (atrasentan) is 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. This indication is approved under accelerated approval based on a reduction of proteinuria. It has not been established whether Vanrafia slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Filspari (sparsentan) and Vanrafia (atrasentan) are the first drugs approved for treating IgAN that do not cause immune suppression. Filspari (sparsentan) is a dual endothelin and angiotensin II receptor antagonist (DEARA) while Vanrafia (atrasentan) is a specific endothelin receptor antagonist (ERA).

IgAN is a rare form of autoimmune kidney disease. Individuals who have IgAN make too much IgA, a normal component of the immune system. IgA generally attaches to bacteria and viruses. Excessive amounts of it forms large complexes that get trapped in the tiny blood vessels of the kidneys. The resulting inflammation, permeability, and scarring of the glomeruli attract more IgA and other substances, slowly increasing kidney damage. As many as 40% of individuals who have IgAN eventually develop kidney failure that requires dialysis or a kidney transplant.

Most individuals with IgAN present with either gross hematuria (single or recurrent), usually accompanying an upper respiratory infection, or microscopic hematuria with or without mild proteinuria detected on a routine examination. Less commonly, individuals may present with either nephrotic syndrome or an acute, rapidly progressive glomerulonephritis.

The diagnosis of IgAN should be suspected in any individual who presents with one or more episodes of gross hematuria (especially if accompanied by an upper respiratory infection), persistent microscopic hematuria with or without proteinuria, or slowly progressive kidney function impairment. The diagnosis is confirmed by kidney biopsy. A kidney biopsy is usually 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.

Current pharmacologic treatment for IgAN includes systemic corticosteroids, immunosuppressants, and antihypertensive drugs in the angiotensin-converting enzyme (ACE) inhibitor and angiotensin receptor blocker (ARB) classes. In December 2021, Tarpeyo™ (budesonide) delayed-release capsules was given Accelerated Approval from the FDA to treat IgAN at risk of rapid progression. It also needs further clinical trial support for full FDA approval.

The goal of treatment of IgAN is to optimize supportive care consisting of blood pressure control, reduction of proteinuria with maximally tolerated renin-angiotensin system blockade (either an ACE inhibitor or an ARB), treatment of dyslipidemia (if present), and lifestyle modification (such as dietary sodium and protein restriction, smoking cessation, weight control, and exercise as appropriate). Individuals with an eGFR >30 mL/min/1.73 m2, use of a sodium-glucose co-transporter 2 (SGLT2) inhibitor may be added to this supportive regimen. Supportive care should be continued for a minimum of three months and ideally six months, unless there is evidence of rapid disease progression.

Individuals with proteinuria ≥1 g/day despite at least three months of optimized supportive care are considered to be at high risk for progressive disease. In such individuals, treatment with immunosuppressive therapy (i.e., oral systemic glucocorticoids) plus supportive care should be considered.

The role of delayed-release oral budesonide in the treatment of IgAN has not been clearly established, it should be reserved for individuals with IgAN who do not respond to or cannot tolerate a six-month course of moderate-dose oral systemic glucocorticoids and who have a persistent urine protein-to-creatinine ratio (UPCR) ≥1.5 g/g or proteinuria ≥2 g/day.

Focal segmental glomerulosclerosis (FSGS) is a histologic lesion, not a distinct disease. It often causes nephrotic syndrome in adults and children and is identified by segmental sclerosis in some (i.e., focal) glomeruli on kidney biopsy under light microscopy (LM).

FSGS is classified into four types based on clinical and biopsy findings. Primary FSGS usually presents with nephrotic syndrome and relates to permeability factors. Secondary FSGS features proteinuria without nephrotic syndrome, often linked to kidney impairment due to glomerular hypertrophy, reduced kidney mass, renal vasodilation, certain drugs (heroin, interferon, pamidronate), or viral infections such as COVID-19 and HIV. Genetic FSGS may cause severe proteinuria and nephrotic syndrome in childhood, or milder symptoms later in life. FSGS of undetermined cause (FSGS UC) shares features with secondary FSGS, but its origin remains unclear even after extensive evaluation, including genetic testing.

Finding an FSGS lesion in a kidney biopsy in a patient with proteinuria **does not confirm a specific diagnosis**. Differentiation between primary and secondary FSGS relies on nephrotic syndrome status, risk factors for secondary FSGS, and the extent of podocyte foot process effacement seen by EM. EM examination of the kidney biopsy with assessment of the extent of podocyte foot process effacement has been shown to help differentiate primary from secondary FSGS. Patients with presumed primary FSGS commonly present with acute onset of the

nephrotic syndrome and associated features of high-grade (>3.5 g/day) proteinuria, hypoalbuminemia, and peripheral edema. Primary FSGS is associated with diffuse (≥80 percent) podocyte foot process effacement on EM examination of the kidney biopsy. Patients with secondary FSGS typically present with slowly increasing proteinuria and kidney function impairment over time. The proteinuria in patients with secondary FSGS is often in the non-nephrotic range, serum albumin levels are usually normal, and, often, there is no peripheral edema, even when protein excretion exceeds >3.5 g/day. Secondary FSGS is generally associated with segmental (<80 percent) podocyte foot process effacement on EM examination of the kidney biopsy.

The goal of therapy in primary FSGS is reduction of proteinuria, preferably achieving complete remission. This is primarily accomplished with the use of a variety of agents having both immunosuppressive properties as well as direct action on glomerular podocytes (commonly glucocorticoids or calcineurin inhibitors [CNIs]) and though use of supportive measures (such as renin-angiotensin inhibition).

General treatment measures should be used in all patients with FSGS including dietary sodium and protein restriction, blood pressure management, renin-angiotensin system inhibition to reduce proteinuria, treatment of dyslipidemia, and anticoagulation when appropriate. Sodium-glucose co-transporter 2 (SGLT2) inhibitors may also be of benefit. Diuretics to manage edema and maintaining adequate nutrition are also important.

Sparsentan is a single molecule with antagonism of the endothelin type A receptor (ET_A R) and the angiotensin II type 1 receptor (AT_1 R). Sparsentan has high affinity for both the ET_A R and the AT_1 R, and greater than 500-fold selectivity for these receptors over the endothelin type B and angiotensin II subtype 2 receptors. Atrasentan is an ET_A receptor antagonist with greater than 1,800-fold selectivity for ET_A receptor compared to the endothelin type B receptor.

Endothelin-1 and angiotensin II are thought to contribute to the pathogenesis of IgAN via the ET_A R and AT_1 R, respectively.

Definitions:

U.S. Food and Drug Administration (FDA) MedWatch Forms for FDA Safety Reporting
MedWatch Forms for FDA Safety Reporting | FDA

Angiotensin Converting Enzyme (ACE) Inhibitors
Benazepril, captopril, enalapril, fosinopril, lisinopril, moexipril, perindopril, quinapril, ramipril, trandolapril

Angiotesin II Receptor Blockers (ARB)
Azilsartan, candesartan, eprosartan, irbesartan, losartan, olmesartan, telmisartan, valsartan

Endothelin Receptor Antagonists
Ambrisentan, bosentan, macitentan

Histamine-2 receptor antagonists
Cimetidine, famotidine, nizatidine, ranitidine

Proton pump inhibitors

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Dexlansoprazole, esomeprazole, lansoprazole, omeprazole, pantoprazole, rabeprazole

Resources:

Filspari (sparsentan) product information, revised by Travere Therapeutics, Inc. 08-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 12, 2026.

Vanrafia (atrarsentan) product information, revised by Novartis Pharmaceuticals Corporation. 04-2025. Available at DailyMed http://dailymed.nlm.nih.gov. Accessed February 12, 2026.

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Heerspink HJL, Radhakrishnan J, Alpers CE, et al.: Sparsentan in patients with IgA nephropathy: A prespecified interim analysis from a randomized, double-blind, active-controlled clinical trial. Lancet 2023 May 13;401:1584-1594. Accessed April 10, 2025. Re-evaluated May 10, 2026.

Rovin BH, Barratt J, Heerspink HJL, et al. Efficacy and safety of sparsentan versus irbesartan in patients with IgA nephropathy (PROTECT): 2-year results from a randomized, active-controlled, phase 3 trial. Lancet 2023 Dec 2;402:2077-2090. Accessed April 10, 2025. Re-evaluated May 10, 2026.

Rheault MN, Alpers CE, Barratt AJ, et al.: Sparsentan versus irbesartan in focal segmental glomerulosclerosis. NEJM 2023 Dec 28;389(26):2436-45. DOI: 10.1056/NEJMoa2308550. Accessed April 13, 2025. Re-evaluated May 10, 2026.

Heerspink HJL, Jardine M, Kohan DE. Et al.: Study design and baseline characteristics of ALIGN, a randomized controlled study of atrasentan in patients with IgA nephropathy. Kidney International Reports 2025; 10: 217–226; https://doi.org/10.1016/j.ekir.2024.10.004. Accessed April 13, 2025. Re-evaluated May 10, 2026.

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