Vanrafia® (atrasentan)

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 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
Vanrafia 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) greater than or equal to 1.5 grams per gram (g/g).

This indication is approved under accelerated approval based on 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.

POLICY

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

1. For initial requests:
   a. Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN)
   b. Chart notes, medical records or laboratory values indicating the member is at risk for disease progression with a UPCR ≥ 1.5 g/g
2. For continuation requests:
   a. Chart notes, medical records or laboratory values supporting positive clinical response

Prescriber Specialties

The requested medication must be prescribed by or in consultation with one of the following:

1. Nephrologist

Criteria for Initial Approval

Primary Immunoglobulin A Nephropathy (IgAN)

Vanrafia (atrasentan) may be considered **medically necessary** for the treatment of IgAN 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 is at risk for rapid disease progression defined by UPCR greater than or equal to 1.5 g/g
4. Member has an eGFR ≥ 30 mL/min per 1.73 m^2
5. Member has received a stable dose of maximally tolerated renin-angiotensin system (RAS) inhibitor therapy (e.g., angiotensin converting enzyme inhibitor [ACEI] or angiotensin II receptor blocker [ARB]) for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to RAS inhibitors
6. Member has tried and failed Filspari (sparsentan) unless member has an intolerance or contraindication
7. The requested medication will not be used in combination with Tarpeyo (budesonide delayed release), Fabhalta (iptacopan), Filspari (sparsentan), or Voyxact (sibeprenlimab-szsi)

Approval will be for **9 months**

Continuation of Therapy

Primary Immunoglobulin A Nephropathy (IgAN)

Vanrafia (atrasentan) may be considered **medically necessary** for the treatment of adults with IgAN when all of the following criteria are met:

1. There is no evidence of unacceptable toxicity or disease progression while on the current regimen
2. The member is experiencing benefit from therapy as evidenced by either of the following:
   a. Decreased levels of proteinuria from baseline
   b. Decrease in UPCR from baseline

Approval will be for **12 months**

Other

Vanrafia (atrasentan) is considered **not medically necessary** for members who do not meet the criteria set forth above.

Members currently receiving the requested medication as samples or via the manufacturer's patient assistance program will be required to meet the criteria for initial approval. This ensures that members are treated equally regardless of their provider's ability to access medication samples.

Non-Formulary Exception Criteria

Non-Formulary Exception criteria applies to formularies which do not include the requested product(s) on the formulary drug list. Meeting the criteria above may satisfy some, or all, portions of the Non-Formulary Exception Criteria. A medication that is non-formulary may be covered when the Criteria for Approval AND the following criteria are met:

1. The requested drug must be used for an FDA-approved indication, or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines). Diagnostic testing/lab results required when applicable.
2. The prescribed dose/quantity must fall within the FDA-approved labeling or dosing guidelines found in the compendia of current literature.
3. All covered formulary alternative drugs on any tier will be ineffective, have been ineffective, would not be as effective as the non-formulary drug, or would have adverse effects. Documentation is required and must include chart note(s) or other documentation indicating prior treatment failure, severity of the adverse event (if any), and dosage and duration of the prior treatment, or contraindication to formulary alternatives.

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 Apply

Medication	Standard Limit	FDA Recommended Dosing
Vanrafia (atrasentan) 0.75 mg oral tablets	30 tablets per 30 days	0.75 mg orally once daily with or without food

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

Vanrafia [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; April 2025.

ClinicalTrial.gov. National Library of Medicine (US). Identifier NCT04573478 Atrasentan in Patients with IgA Nephropathy (ALIGN). October 15, 2024. Available from: https://clinicaltrials.gov/study/NCT04573478.

Kidney Disease: Improving Global Outcomes (KDIGO) Glomerular Diseases Work Group. KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidney Int. 2025 Oct; 108 (4S):S1-S71.

POLICY HISTORY

Policy #: 05.05.92

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