Effective Date: 11/01/2025
Reviewed: 8/25
Pharmacy Scope: Medicaid

Vanrafia (atrasentan tablets)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit 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.

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Primary immunoglobulin A nephropathy (IgAN)
Authorization of 6 months may be granted when all of the following criteria are met:
A. The medication must be prescribed by or in consultation with a nephrologist.
B. Documentation that member has a kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
C. Documentation with laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 1 g/day or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 1.5 g/g based on a 24-hour urine collection.
D. Documentation that member's eGFR ≥30 mL/min/1.73 m2
E. Member is receiving 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.
F. Member is receiving a stable dose of maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to SGLT2 inhibitors.
G. Member has experienced a documented inadequate response from a 30-day trial, intolerance, or contraindication to an oral glucocorticoid (e.g., prednisone).
H. Member is not using medication in combination with an Filspari, Tarpeyo, or Fabhalta.
I. Member is not currently receiving dialysis and has not undergone kidney transplant.

III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when all of the following are met:

A. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
B. Documentation with laboratory report and/or chart note(s) indicating the member is experiencing benefit from therapy as evidenced by either of the following:
    a. Decreased levels of proteinuria from baseline on a 24-hour urine collection
    b. Decrease in UPCR from baseline based on a 24-hour urine collection
C. Documentation that member's eGFR remains ≥30 mL/min/1.73 m2
D. Member is not using medication in combination with an Filspari, Tarpeyo, or Fabhalta.

IV. QUANTITY LIMIT

Vanrafia 0.75 mg tablets: 1 tablet per day.

V. REFERENCES

1. Vanrafia [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; April 2025.
2. 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.
3. 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. doi: 10.1016/j.kint.2021.05.021.