

UnitedHealthcare Pharmacy Clinical Pharmacy Programs

Program Number	2025 P 2370-1
Program	Prior Authorization/Medical Necessity
Medication	Vanrafia TM (atrasentan)
P&T Approval Date	6/2025
Effective Date	9/1/2025

1. Background:

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.

2. Coverage Criteria^a:

A. Initial Authorization

- 1. Vanrafia will be approved based on <u>all</u> of the following:
 - a. Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

-AND-

b. Patient is at risk of disease progression

-AND-

c. Used to slow kidney function decline

-AND-

d. Used to reduce proteinuria

-AND-

e. Estimated glomerular filtration rate (eGFR) \geq 30 mL/min/1.73 m2

-AND-

f. **Both** of the following:



- 1) Patient is on a maximized stable dose with <u>one</u> of the following prior to initiating therapy:
 - a) maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)
 - b) maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

-AND-

2) Use of endothelin receptor antagonists [(ERAs) e.g., Letairis, Opsumit, Tracleer)] will be discontinued prior to initiating treatment

-AND-

g. History of failure, contraindication or intolerance to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone)

-AND-

h. Prescribed by or in consultation with a nephrologist

Authorization will be issued for 12 months

B. Reauthorization

- 1. **Vanrafia** will be approved based on the following:
 - a. Documentation of positive clinical response demonstrated by a reduction in proteinuria

Authorization will be issued for 12 months

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

- 1. Vanrafia [package insert]. East Hanover, NJ: Novartis Pharmaceuticals Corporation; April 2025.
- 2. KDIGO 2021 Glomerular Diseases Guideline. October 2021; 100 (4S).



Program	Prior Authorization/Medical Necessity – Vanrafia	
Change Control		
Date	Change	
6/2025	New program	