PHARMACY POLICY STATEMENT
HAP CareSource™ Marketplace

DRUG NAME	Vanrafia (atrasentan)
BENEFIT TYPE	Pharmacy
STATUS	Prior Authorization Required

Vanrafia, approved by the FDA in 2025, is an endothelin receptor antagonist 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 it slows kidney function decline. IgA nephropathy is the most common primary glomerular disease. It is an autoimmune condition caused by deposits of immunoglobulin A (IgA) in the kidney, leading to hematuria, proteinuria, and nephropathy (kidney disease) as the kidneys become unable to filter. This can slowly progress to end stage renal disease (ESRD) requiring dialysis or kidney transplant. ACE inhibitors or angiotensin receptor blockers (ARBs) are used to slow the progression of kidney disease.

Vanrafia (atrasentan) will be considered for coverage when the following criteria are met:

Primary Immunoglobulin A Nephropathy (IgAN)

For **initial** authorization:

1. Member is at least 18 years of age; AND
2. Medication must be prescribed by or in consultation with a nephrologist; AND
3. Member has a diagnosis of IgA nephropathy confirmed by renal biopsy; AND
4. Chart notes must indicate risk of rapid disease progression per documentation of UPCR 1.5 g/g or greater despite max tolerated dose of an ACEi or ARB for at least 3 months; AND
5. Member has had a trial and failure of Tarpeyo or Filspari; AND
6. Member's eGFR is at least 30 mL/min/1.73m^2; AND
7. Member will continue ACEi or ARB unless contraindicated or intolerable.
8. **Dosage allowed/Quantity limit:** 0.75 mg orally once daily. QL: 30 tablets per 30 days.

If all the above requirements are met, the medication will be approved for 9 months.

For **reauthorization**:

1. Chart notes must show reduced proteinuria (e.g., UPCR) compared to baseline.

If all the above requirements are met, the medication will be approved for an additional 12 months.

HAP CareSource considers Vanrafia (atrasentan) not medically necessary for the treatment of conditions that are not listed in this document. For any other indication, please refer to the Off-Label policy.

DATE	ACTION/DESCRIPTION
04/11/2025	New policy for Vanrafia created.
06/25/2025	Added trial of Tarpeyo or Filspari.

References:

1. Vanrafia [prescribing information]. Novartis Pharmaceuticals Corporation; 2025.
2. 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(4S):S1-S276. doi:10.1016/j.kint.2021.05.021
3. 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 Int Rep*. 2024;10(1):217-226. Published 2024 Oct 10. doi:10.1016/j.ekir.2024.10.004

Effective date: 10/01/2025
Revised date: 04/11/2025