Harvard Pilgrim Health Care | TUFTS Health Plan

Pharmacy Medical Necessity Guidelines:
Vanrafia (atrasentan)

Effective: August 11, 2026

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☒ Harvard Pilgrim Health Care Commercial products; Fax: 617-673-0988

☒ Tufts Health Plan Commercial products; Fax: 617-673-0988

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax: 617-673-0988

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration – Approved Indications

Vanrafia (atrasentan) 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 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.

Clinical Guideline Coverage Criteria

The plan may authorize coverage of Vanrafia for Members when **ALL** of the following criteria are met:

Initial Authorization

1. Documented diagnosis of immunoglobulin A nephropathy confirmed by kidney biopsy

AND

2. Documented urine protein-to-creatinine ratio (UPCR) of at least 1.5 g/g or proteinuria ≥ 1 g/day

AND

3. Documented estimated glomerular filtration rate of at least 30 mL/min/1.73 m^2

AND

4. Prescribed by or in consultation with a nephrologist

AND

5. Documentation the patient has not developed end stage renal disease by requiring either dialysis or a kidney transplant

AND

6. Documentation that the member has received or is currently receiving at least 3 months of therapy with an angiotensin converting enzyme inhibitor (ACEi) or angiotensin receptor blocker (ARB) (at up to maximally indicated doses), unless contraindicated or not tolerated

AND

7. Documentation that the member has received or is currently receiving at least 3 months of therapy with a sodium-glucose cotransporter-2 inhibitor (SGLT2i), unless contraindicated or not tolerated

AND

8. Documentation that the member has received optimized supportive care for at least 3 months, including blood pressure management, lifestyle modification, and cardiovascular risk modification

Reauthorization Criteria

1. Documented diagnosis of immunoglobulin A nephropathy confirmed by kidney biopsy

AND

2. Prescribed by or in consultation with a nephrologist

AND

3. Documentation of a positive clinical response as evidence by a reduction in proteinuria

AND

4. Documentation the patient has not developed end stage renal disease by requiring either dialysis or a kidney transplant

Limitations

1. Initial coverage of Vanrafia will be authorized for 9 months. Reauthorization of Vanrafia will be provided in 12-month intervals.
2. Patients new to the plan stable on Vanrafia should be reviewed against Reauthorization Criteria.

Codes

None

References

1. Vanrafia (atrasentan) [package insert]. East Hanover, New Jersey: Novartis Pharmaceuticals Corporation; April 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.

Approval And Revision History

August 12, 2025: Reviewed by the Pharmacy & Therapeutics Committee.

- August 11, 2026: Administrative update to remove Carelink from Medical Necessity Guideline template

Background, Product and Disclaimer Information

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.