Reference number(s)
6939-A

Specialty Guideline Management
Vanrafia

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Vanrafia	atrasentan

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 Indication[1]

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).

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

Documentation

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

- Initial requests:
  - Kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).

    - Laboratory report and/or chart note(s) indicating the member has proteinuria greater than or equal to 0.5 grams per day (g/day) or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 grams per gram (g/g) obtained within 3 months prior to initiation of the requested drug.
- Continuation requests:
    - Laboratory report and/or chart note(s) indicating the member has decreased levels of proteinuria or UPCR from baseline.

Prescriber Specialties

This medication must be prescribed by or in consultation with a nephrologist.

Coverage Criteria

Primary Immunoglobulin A Nephropathy (IgAN)[1-5]

Authorization of 12 months may be granted when all of the following criteria are met:

- Member has a diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy.
- Member has either of the following obtained within 3 months prior to initiation of the requested drug:
    - Proteinuria greater than or equal to 0.5 g/day
    - UPCR greater than or equal to 0.8 g/g
- 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 of therapy, or member has an intolerance or contraindication to RAS inhibitors.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in all members (including new members) who are currently receiving the requested medication and who are experiencing benefit from therapy as evidenced by either of the following:

- Decreased levels of proteinuria from baseline.
- Decrease in UPCR from baseline.

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. Fellstrom BC, Baratt J, Cook H, et al. Targeted-release budesonide versus placebo in patients with IgA nephropathy (NEFIGAN): a double-blind, randomized, placebo-controlled phase 2b trial. *Lancet*. 2017 May 27;389 (10084): 2117-2127.
4. Kidney Disease: Improving Global Outcomes (KDIGO). 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.
5. Heerspink HJL, Jardine M, Kohan DE et al. Atrasentan in patients with IgA Nephropathy. N Engl J Med. 2025 Feb; 329 (6): 544-554.