PRIOR AUTHORIZATION POLICY

POLICY: Nephrology – Trutakna Prior Authorization Policy
- Trutakna™ (atacicept-vymj subcutaneous injection – Vera)

REVIEW DATE: 07/08/2026

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT WHERE APPROPRIATE AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. WHERE COVERAGE FOR CARE OR SERVICES DOES NOT DEPEND ON SPECIFIC CIRCUMSTANCES, REIMBURSEMENT WILL ONLY BE PROVIDED IF A REQUESTED SERVICE(S) IS SUBMITTED IN ACCORDANCE WITH THE RELEVANT CRITERIA OUTLINED IN THE APPLICABLE COVERAGE POLICY, INCLUDING COVERED DIAGNOSIS AND/OR PROCEDURE CODE(S). REIMBURSEMENT IS NOT ALLOWED FOR SERVICES WHEN BILLED FOR CONDITIONS OR DIAGNOSES THAT ARE NOT COVERED UNDER THIS COVERAGE POLICY (SEE "CODING INFORMATION" BELOW). WHEN BILLING, PROVIDERS MUST USE THE MOST APPROPRIATE CODES AS OF THE EFFECTIVE DATE OF THE SUBMISSION. CLAIMS SUBMITTED FOR SERVICES THAT ARE NOT ACCOMPANIED BY COVERED CODE(S) UNDER THE APPLICABLE COVERAGE POLICY WILL BE DENIED AS NOT COVERED. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

OVERVIEW

Trutakna, a B-lymphocyte stimulator (BLys)-specific inhibitor and an A Proliferation Inducing Ligand (APRIL) blocker, is indicated to reduce proteinuria in adults with **primary immunoglobulin A nephropathy** (IgAN) at risk of rapid disease progression.[1]

Trutakna was approved under accelerated approval based on reduction of proteinuria.[1] It has not been established whether Trutakna slows kidney function decline over the long-term 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 Efficacy

The efficacy of Trutakna was evaluated in a Phase III, randomized, double-blind, placebo-controlled trial (ORIGIN 3, n = 203) in adults with biopsy-confirmed IgA

nephropathy, at screening, defined as a urinary protein-to-creatinine ratio (UPCR) ≥ 1.0 g/g or urine protein excretion ≥ 1.0 g/day, and an estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2.[1,2] Patients were required to be on a stable, maximum tolerated dose of a renin-angiotensin system (RAS) inhibitor for ≥ 12 weeks prior to enrollment; approximately half were also receiving a sodium-glucose cotransporter 2 (SGLT2) inhibitor. Patients with secondary IgA nephropathy or rapidly progressive disease were excluded.

The primary endpoint was percent change from baseline in 24-hour UPCR at Week 36.[1,2] Trutakna demonstrated a statistically significant reduction in proteinuria compared with placebo (-45.7% vs. -6.8%, respectively), corresponding to a between-group difference of 41.8% ($P < 0.001$). Secondary and exploratory outcomes at Week 36 showed reductions in galactose-deficient IgA1 levels were greater with Trutakna (-68.3%) compared with placebo (-2.9%). Among patients with baseline hematuria, resolution occurred in 81.0% of patients receiving Trutakna vs. 20.7% with placebo.

Guidelines

Kidney Diseases: Improving Global Outcome clinical practice guidelines for the management of IgAN and immunoglobulin A vasculitis (2025) recommend following a biopsy-confirmed diagnosis of IgAN; the primary focus of treatment should include RAS inhibitors or Filspari® (sparsentan tablets) with or without SGLT2 inhibitor, blood pressure control, cardiovascular risk minimization, and adherence to lifestyle advice.[3] Filspari should not be prescribed with a RAS inhibitor. It is also recommended that a 9-month course of Tarpeyo (budesonide delayed-release capsules) be considered for patients with a risk of progressive kidney function loss with IgAN. Therapeutic strategies that minimize or avoid systemic glucocorticoid exposure are considered areas of priority for research to improve treatment and outcomes in patients with IgAN. Trutakna, Fabhalta® (iptacopan capsules), Vanrafia™ (atrasentan tablets), and Voyxact® (sibeprenlimab-szsi subcutaneous injection) were noted as investigative treatments with no guideline recommendations. The goal of treatment is to prevent progressive kidney function loss. The only validated biomarker to guide clinical decision-making is urine protein excretion, which should be maintained < 0.5 g/day and ideally < 0.3 g/day. Additional treatment should be considered if the patient has proteinuria ≥ 0.5 g/day (or equivalent) while on or off treatment.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Trutakna. All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Trutakna as well as the monitoring required for adverse events and long-term efficacy, approval requires Trutakna to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Trutakna™ (atacicept-vymj subcutaneous injection - Vera) is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indication

1. **Primary Immunoglobulin A Nephropathy.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The diagnosis has been confirmed by biopsy; AND
     - **iii.** Patient is at high risk of disease progression, defined by meeting BOTH of the following (a and b):
       - **a)** Patient meets ONE of the following [(1) or (2)]:
         - **(1)** Proteinuria ≥ 0.5 g/day; OR
         - **(2)** Urine protein-to-creatinine ratio ≥ 0.5 g/g; AND
       - **b)** Patient has received or is currently receiving the maximum or maximally tolerated dose of ONE of the following for ≥ 12 weeks prior to starting Trutakna [(1) or (2)]:
         - **(1)** Angiotensin converting enzyme inhibitor; OR
         - **(2)** Angiotensin receptor blocker; AND
     - **iv.** According to the prescriber, patient has received ≥ 3 months of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification; AND
     - **v.** Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
     - **vi.** The medication is prescribed by or in consultation with a nephrologist; OR
   - **B)** Patient is Currently Receiving Trutakna. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The diagnosis has been confirmed by biopsy; AND
     - **iii.** According to the prescriber, patient has had a response to the requested medication; AND
       Note: Examples of a response are a reduction in urine protein-to-creatinine ratio from baseline, reduction in proteinuria from baseline.
     - **iv.** Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
     - **v.** The medication is prescribed by or in consultation with a nephrologist.

CONDITIONS NOT COVERED

Trutakna™ (atacicept-vymj subcutaneous injection (Vera) is(are) considered not medically necessary for ANY other use(s) including the following (this list may not be all inclusive. Criteria will be updated as new published data are available.

REFERENCES

1. Trutakna™ subcutaneous injection [prescribing information]. Brisbane, Ca: Vera; July 2026.
2. Lafayette R, Barbour SJ, Brenner RM, et al. A phase 3 trial of atacicept in patients with IgA nephropathy. *N Engl J Med*. 2026;394(7):647-657.
3. Kidney Diseases: Improving Global Outcomes (KDIGO) 2025 clinical practice guidelines for the management of immunoglobulin A nephropathy (IgAN) and immunoglobulin A vasculitis (IgAV). Available at: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf. Accessed on July 7, 2026.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	07/08/2026