Medical Drug Clinical Criteria

Subject:	Trutakna (atacicept-vymj)		
Document #:	CC-0306	**Publish Date:**	07/28/2026
Status:	New	**Last Review Date:**	07/13/2026

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Overview

This document addresses the use of Trutakna (atacicept-vymj), a B-lymphocyte stimulator (BLyS)-specific inhibitor and A Proliferation Inducing Ligand (APRIL) blocker approved by the Food and Drug Administration (FDA) to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. Trutakna was approved under accelerated approval based on reduction of proteinuria, and continued approval may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

Trutakna's efficacy was evaluated in a randomized, double-blind, placebo-controlled in adults with biopsy-proven IgAN, estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m² and proteinuria defined as either urine protein/creatinine ratio (UPCR) ≥ 1.0 g/g or urine protein ≥ 1 g/day. Participants were required to be on a stable, maximally tolerated dose of renin angiotensin system (RAS) inhibition (angiotensin-converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]) with or without concomitant sodium-glucose co-transporter 2 (SGLT2) inhibitor therapy. Trutakna demonstrated improvement in the primary endpoint at month 9, with a 41.8% relative reduction in UPCR compared to placebo ($p<0.0001$).

In 2025, Kidney Disease: Improving Global Outcomes (KDIGO) published guidelines on the management of immunoglobulin A nephropathy (IgAN). KDIGO emphasizes that IgAN is diagnosed via biopsy as there are no validated serum/urine biomarkers. While IgAN agents were studied in populations with more advanced proteinuria, KDIGO recommends treatment escalation in individuals with proteinuria ≥0.5 g/day. Treatment is framed as a dual strategy to reduce IgA immune complex formation and glomerular injury and manage consequences of existing IgAN-induced nephron loss. For the first pillar, KDIGO recommends a nine-month course of Tarpeyo. Reduced dose systemic glucocorticoids are an option when Tarpeyo is not available. Fabhalta and Voyxact are not included in the guideline but fall under this pillar. For the second pillar, KDIGO recommends maximally tolerated ACE inhibitor or ARB or Filspari with or without sodium-glucose co-transporter 2 inhibitor (SGLT2). Vanrafia is not included in the guidelines but falls under the second pillar. Trutakna is mentioned in the guidelines but not included in the recommendations as it was not FDA approved at the time of publication.

Clinical Criteria

When a drug is being reviewed for coverage under a member's medical benefit plan or is otherwise subject to clinical review (including prior authorization), the following criteria will be used to determine whether the drug meets any applicable medical necessity requirements for the intended/prescribed purpose.

Trutakna (atacicept-vymj)

Initial requests for Trutakna (atacicept-vymj) may be approved if the following criteria are met:

I. Individual has a diagnosis of primary immunoglobulin A nephropathy (IgAN); **AND**
II. Documentation is provided that diagnosis has been verified with kidney biopsy; **AND**
III. Individual has had a trial of maximally tolerated angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) therapy unless contraindicated or not tolerated; **AND**
IV. Individual has proteinuria meeting one of the following criteria:
    A. Urine protein-to-creatinine ratio (UPCR) ≥ 1 g/g;

B. Urine protein ≥ 1 g/day; **AND**

V. Individual has an eGFR ≥ 30 mL/min/1.73 m^2; **AND**

VI. Documentation is provided that individual will be taking Trutakna in combination with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or Filspari (sparsentan) unless contraindicated or not tolerated (KDIGO 2025).

Continuation requests for Trutakna (atacicept-vymj) may be approved if the following criteria are met:

I. There is clinically significant reduction in proteinuria; **AND**

II. Documentation is provided that individual will be taking Trutakna in combination with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) or Filspari (sparsentan) unless contraindicated or not tolerated (KDIGO 2025).

Requests for Trutakna (atacicept-vymj) may not be approved for the following:

I. In combination with Tarpeyo (budesonide delayed release), Fabhalta (iptacopan) or Voyxact (sibeprenlimab-szsi).

Approval Duration
Initial requests: 6 months
Continuation requests: 1 year

Quantity Limits

Trutakna (atacicept-vymj) Quantity Limit

Drug	Limit
Trutakna (atacicept-vymj) 150 mg/mL	4 autoinjectors per 28 days

Coding

The following codes for treatments and procedures applicable to this document are included below for informational purposes. Inclusion or exclusion of a procedure, diagnosis or device code(s) does not constitute or imply member coverage or provider reimbursement policy. Please refer to the member's contract benefits in effect at the time of service to determine coverage or non-coverage of these services as it applies to an individual member.

HCPCS

C9399	Unclassified drugs or biologicals [when specified as Trutakna (atacicept-vymj)]
J3590	Unclassified biologics [when specified as Trutakna (atacicept-vymj)]

ICD-10 Diagnosis

N02.B1-N02.B9	Recurrent and persistent immunoglobulin A nephropathy

Document History

New: 7/13/2026
Document History:

- 7/13/2026 – Select Review: New clinical criteria and quantity limit for Trutakna. Administrative addition for documentation. Coding Reviewed: Added HCPCS NOC C9399, J3590, and ICD-10-CM N02.B1-N02.B9.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: January 26, 2026.
2. Kidney Disease: Improving Global Outcomes (KDIGO) IgAN and IgAV Work Group, Rovin BH, Barratt J, et al. KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). *Kidney Int*. 2025;108(4S): S1-S71.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.

4. Merative™ Micromedex® DRUGDEX® (electronic version). Merative, Ann Arbor, Michigan, USA.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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