Medical Drug Clinical Criteria

Subject:	Voyxact (sibeprenlimab-szsi)		
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Overview

This document addresses the use of Voyxact (sibeprenlimab-szsi), 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. Voyxact 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.

Voyxact's efficacy was assessed in a randomized, double-blind, placebo-controlled trial in 320 individuals with biopsy-proven IgAN, eGFR ≥ 30 mL/min/1.73 m^2 and proteinuria defined as either urine protein/creatinine ratio (UPCR) ≥ 0.75 g/g or urine protein ≥ 1.0 g/day. Participants were required to be on a stable dose of maximally tolerated RAS inhibitor (angiotensin-converting enzyme [ACE] inhibitor or angiotensin receptor blocker [ARB]) therapy with or without a sodium-glucose co-transporter 2 (SGLT2) inhibitor. Voyxact demonstrated improvement in the primary endpoint at month 9, with a 51.2% relative reduction in UPCR compared to placebo ($p<0.001$).

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.

Voyxact (sibeprenlimab-szsi)

Initial requests for Voyxact (sibeprenlimab-szsi) 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) ≥ 0.75 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 Voyxact (sibeprenlimab-szsi) in combination with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated.

Continuation requests for Voyxact (sibeprenlimab-szsi) 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 Voyxact (sibeprenlimab-szsi) in combination with an angiotensin-converting enzyme (ACE) inhibitor or angiotensin receptor blocker (ARB) unless contraindicated or not tolerated.

Voyxact (sibeprenlimab-szsi) may not be approved for the following:

I. In combination with Tarpeyo (budesonide delayed release) or Fabhalta (iptacopan).

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

Quantity Limits

Voyxact (sibeprenlimab-szsi) Quantity Limit

Drug	Limit
Voyxact (sibeprenlimab-szsi) 400 mg/2 mL	1 prefilled syringe per 4 weeks

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 Voyxact (sibeprenlimab-szsi)]
J3590	Unclassified biologics [when specified as Voyxact (sibeprenlimab-szsi)]

ICD-10 Diagnosis

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

Document History

New: 12/8/2025
Document History:
- 12/8/2025 – Select Review: New clinical criteria and quantity limit for Voyxact. Administrative update to add documentation. Coding Reviewed: Added HCPCS NOC C9399, J3590 for Voyxact 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: December 1, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc. Updated periodically.