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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Genitourinary Agents	**Original Policy Date:**	January 23, 2026
Subject:	Voyxact	**Page:**	1 of 4

Last Review Date: March 6, 2026

Voyxact

Description

Voyxact (sibeprenlimab-szsi) injection

Background
Voyxact (sibeprenlimab-szsi) binds to A Proliferation Inducing Ligand (APRIL) with a dissociation constant of 0.95 pM, which blocks signaling at the B cell maturation antigen (BCMA) and transmembrane activator and calcium modulator and cyclophilin ligand interactor (TACI) receptors. Inhibition of APRIL results in reduced levels of serum galactose-deficient immunoglobulin A1, which is implicated in the pathogenesis of primary immunoglobulin A nephropathy (IgAN) (1).

Regulatory Status
FDA-approved indication: Voyxact is an A Proliferation Inducing Ligand (APRIL) blocker, indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression (1).

The clinical trial for Voyxact had inclusion criteria for patients to be on a maximum recommended or maximum tolerated dose of an angiotensin-converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB). Patients also had an estimated glomerular filtration rate (eGFR) of ≥ 30 mL/min/1.73 m^2 (2).

Voyxact contains warnings regarding immunosuppression and increased risk of infections, and immunosuppression and immunization risks. Live vaccines are not recommended within 30 days prior to initiation of Voyxact or during treatment with Voyxact as safety has not been established (1).

The safety and effectiveness of Voyxact in pediatric patients less than 18 years of age have not been established (1).

Related policies
Fabhalta, Filspari, Tarpeyo, Vanrafia

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Voyxact may be considered **medically necessary** if the conditions indicated below are met.

Voyxact may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Primary immunoglobulin A nephropathy (IgAN)

AND ALL of the following:

a. Diagnosis has been confirmed by a kidney biopsy
b. Patient is at risk for disease progression indicated by proteinuria ≥ 1.0 g/day
c. Used in combination with maximum recommended or maximum tolerated dose of ACEI or ARB therapy
d. eGFR ≥ 30 mL/min/1.73 m^2
e. Prescribed by or recommended by a nephrologist

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Primary immunoglobulin A nephropathy (IgAN)

AND ALL of the following:

a. Decrease in proteinuria
b. Used in combination with maximum recommended or maximum tolerated dose of ACEI or ARB therapy

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 3 syringes per 84 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Voyxact is an A Proliferation Inducing Ligand (APRIL) blocker, indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression. The safety and effectiveness of Voyxact in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Voyxact while maintaining optimal therapeutic outcomes.

References

1. Voyxact [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2025.

2. Perkovic V, Trimarchi H, et al.; VISIONARY Trial Investigators Group. Sibeprenlimab in IgA Nephropathy - Interim Analysis of a Phase 3 Trial. N Engl J Med. 2025 Nov 8. doi: 10.1056/NEJMoa2512133.

Policy History

Date	Action
January 2026	Addition to PA
March 2026	Annual review

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.