Effective Date: 5/1/2026
Reviewed: 2/26
Pharmacy Scope: Medicaid

Voyxact (sibeprenlimab-szsi) SC injection

POLICY

I. 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 Indications
Voyxact is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk for disease progression.

* This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether Voyxact 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.

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

II. CRITERIA FOR INITIAL APPROVAL

Primary immunoglobulin A nephropathy (IgAN)
Authorization of 6 months may be granted when all of the following criteria are met:
A. The medication must be prescribed by or in consultation with a nephrologist.
B. Member is 18 years of age or older.
C. Documentation that member has a kidney biopsy confirming a diagnosis of primary immunoglobulin A nephropathy (IgAN).
D. Documentation with laboratory report and/or chart note(s) within the previous 3 months indicating the member has proteinuria greater than or equal to 1 g/day or baseline urine protein-to-creatinine ratio (UPCR) greater than or equal to 0.8 g/g based on a 24-hour urine collection.
E. Documentation that member's eGFR $\geq$30 mL/min/1.73 m^2
F. 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 prior to initiation of therapy, or member has an intolerance or contraindication to RAS inhibitors.
G. Member is receiving a stable dose of maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor for at least 3 months prior to initiation of therapy, or member has an intolerance or contraindication to SGLT2 inhibitors.
H. Member has experienced a documented inadequate response from a 30-day trial, intolerance, or contraindication to an oral glucocorticoid (e.g., prednisone).
I. Member is not using medication in combination with Filspari, Tarpeyo, Vanrafia, or Fabhalta.
J. Member is not currently receiving dialysis and has not undergone kidney transplant.

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III. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization when all of the following are met:

A. There is no evidence of unacceptable toxicity or disease progression while on the current regimen.
B. Documentation with recent laboratory report and/or chart note(s) indicating the member is experiencing benefit from therapy as evidenced by either of the following:
    a. Decreased levels of proteinuria from baseline on a 24-hour urine collection
    b. Decrease in UPCR from baseline based on a 24-hour urine collection
C. Documentation that member's eGFR remains ≥30 mL/min/1.73 m^2
D. Member is not using medication in combination with Filspari, Tarpeyo, Vanrafia or Fabhalta.

IV. QUANTITY LIMIT

Voyxact 400 mg/2mL prefilled syringe: one 2 mL syringe per 28 days

V. REFERENCES

1. Voyxact [package insert]. Tokyo, Japan: Otsuka Pharmaceutical Company, Ltd. November 2025
2. ClinicalTrial.gov. National Library of Medicine (US). Identifier NCT05248646 Visionary Study: Phase 3 Trial of Sibeprenlimab in Immunoglobulin A Nephropath (IgAN). July 10, 2025. Available from: https://clinicaltrials.gov/study/NCT05248646.
3. Fellstrom BC, Baratt J, Cook H, et al. Targeted-release budesonide versus placebo in patients in 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 Immunoglobilin A Vasculitis (IgAV). Kidney Int. 2025 Oct;108 (4S): S1-S71.