UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2025 P 2390-1
Program	Prior Authorization/Medical Necessity
Medication	Voyxact® (sibeprenlimab-szsl)
P&T Approval Date	1/2026
Effective Date	4/1/2026

1. Background:

Voyxact (sibeprenlimab-szsl) is indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression.

This indication is approved under accelerated approval based on a 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.

2. Coverage Criteria[a]:

A. Initial Authorization

1. **Voyxact** will be approved based on **all** of the following:

   a. Diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by renal biopsy

   -AND-

   b. Patient is at risk of rapid disease progression

   -AND-

   c. Used to reduce proteinuria

   -AND-

   d. Estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m2

   -AND-

   e. **One** of the following:

      1) Patient is on a stabilized dose and receiving concomitant therapy with one of the following:

         a) Maximally tolerated angiotensin converting enzyme (ACE) inhibitor (e.g., captopril, enalapril)

b) Maximally tolerated angiotensin II receptor blocker (ARB) (e.g., candesartan, valsartan)

-OR-

2) Patient has a contraindication or intolerance to ACE inhibitors and ARBs

-AND-

f. One of the following:

1) Patient is on a stabilized dose and receiving concomitant therapy with a maximally tolerated sodium-glucose cotransporter-2 (SGLT2) inhibitor [e.g., Jardiance (empagliflozin)]

-OR-

2) Patient has a contraindication or intolerance to SGLT2 inhibitors

-AND-

g. History of failure to a 30-day trial of a glucocorticoid (e.g., methylprednisolone, prednisone), contraindication or intolerance

-AND-

h. Prescribed by or in consultation with a nephrologist

Authorization will be issued for 12 months

B. Reauthorization

1. **Voyxact** will be approved based on the following:

a. Documentation of positive clinical response demonstrated by a reduction in proteinuria

Authorization will be issued for 12 months

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Voyxact [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; November 2025.
2. Kidney Disease: Improving Global Outcomes (KDIGO) IgAN and IgAV Work Group. (2025). KDIGO 2025 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV). Kidney International, 108(Suppl 4), S1–S71.

Program	Prior Authorization/Medical Necessity – Voyxact
Change Control	
Date	Change
1/2026	New program