VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Nephrology – Voyxact Prior Authorization Policy
- Voyxact® (sibeprenlimab-szsi subcutaneous injection – Otsuka)

REVIEW DATE: 04/22/2026

OVERVIEW

Voyxact, an A Proliferation Inducing Ligand (APRIL) blocker, is indicated to reduce proteinuria in adults with **primary immunoglobulin A nephropathy** (IgAN) at risk of rapid disease progression.[1]

Voyxact was approved under accelerated approval based on reduction of proteinuria.[1] 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.

Clinical Efficacy

The efficacy of Voyxact was evaluated in a Phase III trial in adults with biopsy-proven IgAN, proteinuria at screening (defined as a urine protein to creatinine ratio [UPCR] ≥ 0.75 g/g or urine protein ≥ 1.0 g/day), and estimated glomerular filtration rate (eGFR) ≥ 30 mL/min/1.73 m^2 (VISIONARY, n = 510).[1,3] Additionally, patients were receiving the maximum tolerated dose of an angiotensin converting enzyme inhibitor (ACEI) or angiotensin receptor blocker (ARB) with or without a sodium-glucose co-transporter 2 (SGLT2) inhibitor for ≥ 12 weeks prior to study entry. Patients who were receiving immunosuppressive medications (including corticosteroids within 16 weeks of screening), and patients with CKD in addition to IgAN, or IgAN secondary to other conditions were excluded. The majority of patients remained on a renin-angiotensin system (RAS) inhibitor throughout the study.[1]

The primary efficacy endpoint was the change from baseline in UPCR (based on 24-hour urine sample) at Month 9.[1,3] In the interim analysis set (comprised of the first 320 patients randomized in the study, who completed 9 months of the trial), the change in UPCR from baseline to Month 9 was significantly greater with Voyxact compared with placebo. The geometric least squares mean percent change in UPCR from baseline was -50% for Voyxact vs. 2% for placebo. This resulted in a statistically significant relative reduction from baseline in UPCR for the Voyxact group, corresponding to a 51% relative reduction with Voyxact ($P < 0.0001$). In the exploratory analysis, the percent of patients achieving remission of proteinuria (total urine protein < 0.5 g/day at Month 12) was 34.3% for Voyxact (n = 99) and 12.7% for placebo (n = 118).[3]

Guidelines

KDIGO clinical practice guidelines for the management of IgAN and immunoglobulin A vasculitis (2025) recommend following a biopsy-confirmed diagnosis of IgAN, the primary focus of treatment should include RAS inhibitors or Filspari with or without SGLT2 inhibitor, blood pressure control, cardiovascular risk minimization, and adherence to lifestyle advice.[2] Filspari should not be prescribed with a RAS inhibitor. It is also recommended that a 9-month course of Tarpeyo (budesonide delayed-release capsules) be considered for patients with a risk of progressive kidney function loss with IgAN. Therapeutic strategies that minimize or avoid systemic glucocorticoid exposure are considered areas of priority for research to improve treatment and outcomes in patients with IgAN. Voyxact, Fabhalta (iptacopan capsules), and Vanrafia (atrasentan tablets) were noted as investigative treatments with no guideline recommendations. The goal of treatment is to prevent progressive kidney function loss. The only validated biomarker to guide clinical decision-making is urine protein excretion, which should be maintained < 0.5 g/day and ideally <

0.3 g/day. Additional treatment should be considered if the patient has proteinuria ≥ 0.5 g/day (or equivalent) while on or off treatment.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Voyxact. All approvals are provided for the duration noted below. In cases where the approval is authorized in months, 1 month is equal to 30 days. Because of the specialized skills required for evaluation and diagnosis of patients treated with Voyxact as well as the monitoring required for adverse events and long-term efficacy, approval requires Voyxact to be prescribed by or in consultation with a physician who specializes in the condition being treated.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Voyxact is recommended in those who meet the following criteria:

FDA-Approved Indication

1. **Primary Immunoglobulin A Nephropathy.** Approve for 1 year if the patient meets ONE of the following (A or B):
   - **A)** Initial Therapy. Approve if the patient meets ALL of the following (i, ii, iii, iv, v, and vi):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The diagnosis has been confirmed by biopsy; AND
     - **iii.** Patient is at high risk of disease progression, defined by meeting BOTH of the following (a and b):
       - **a)** Patient meets ONE of the following [(1) or (2)]:
         - **(1)** Proteinuria ≥ 0.5 g/day; OR
         - **(2)** Urine protein-to-creatinine ratio ≥ 0.5 g/g; AND
       - **b)** Patient has received or is currently receiving the maximum or maximally tolerated dose of ONE of the following for ≥ 12 weeks prior to starting Voyxact [(1) or (2)]:
         - **(1)** Angiotensin converting enzyme inhibitor; OR
         - **(2)** Angiotensin receptor blocker; AND
     - **iv.** According to the prescriber, patient has received ≥ 3 months of optimized supportive care, including blood pressure management, lifestyle modification, and cardiovascular risk modification; AND
     - **v.** Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
     - **vi.** The medication is prescribed by or in consultation with a nephrologist; OR
   - **B)** Patient is Currently Receiving Voyxact. Approve if the patient meets ALL of the following (i, ii, iii, iv, and v):
     - **i.** Patient is ≥ 18 years of age; AND
     - **ii.** The diagnosis has been confirmed by biopsy; AND
     - **iii.** According to the prescriber, patient has had a response to the requested medication; AND
       Note: Examples of a response are a reduction in urine protein-to-creatinine ratio from baseline, reduction in proteinuria from baseline.
     - **iv.** Patient has an estimated glomerular filtration rate ≥ 30 mL/min/1.73 m^2; AND
     - **v.** The medication is prescribed by or in consultation with a nephrologist.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Voyxact is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Voyxact® subcutaneous injection [prescribing information]. Rockville, MD: Otsuka; November 2025.
2. Kidney Diseases: Improving Global Outcomes (KDIGO) 2025 clinical practice guidelines for the management of immunoglobulin A nephropathy (IgAN) and immunoglobulin A vasculitis (IgAV). Available at: https://kdigo.org/wp-content/uploads/2024/08/KDIGO-2025-IgAN-IgAV-Guideline.pdf. Accessed on April 14, 2026.
3. Perkovic V, Trimarchi H, Tesar V, et al. Sibeprenlimab in IgA Nephropathy - Interim analysis of a Phase 3 trial. *N Engl J Med*. Published online November 8, 2025.

HISTORY

Type of Revision	Summary of Changes	Review Date
New Policy	--	12/10/2025
Selected Revision	**Primary Immunoglobulin A Nephropathy:** The approval duration was changed to 1 year for both initial therapy and patients currently receiving Voyxact.	03/25/2026
Early Annual Revision	**Primary Immunoglobulin A Nephropathy:** The criterion requiring that the patient is at high risk of disease progression, defined by ONE of the following: urine protein-to-creatinine ratio ≥ 0.8 g/g OR proteinuria ≥ 0.5 g/day was modified to require that the patient is at high risk of disease progression, defined by urine protein-to-creatinine ratio ≥ 0.5 g/g OR proteinuria ≥ 0.5 g/day.	04/22/2026