

ALASKA MEDICAID  
Prior Authorization Criteria

**Voyxact<sup>®</sup>**  
**(sibeprenlimab-szsi)**

**FDA INDICATIONS AND USAGE<sup>1</sup>**

Voyxact<sup>®</sup> 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.

This indication is approved under accelerated approval based on reduction of proteinuria. It has not been established whether Voyxact<sup>®</sup> 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.

**APPROVAL CRITERIA<sup>1,2,3,4</sup>**

1. Patient meets FDA labeled age **AND**;
2. Prescribed by or in consultation with a nephrologist **AND**;
3. Patient has the diagnosis of primary immunoglobulin A nephropathy (IgAN) confirmed by kidney biopsy **AND**;
4. Patient estimated glomerular filtration rate (eGFR)  $\geq 30\text{ml/min/1.73m}^2$  **AND**;
5. One or more of the following applies:
  - a. Patient has proteinuria  $\geq 0.5\text{g/day}$
  - b. Patient urine protein to creatinine ratio (UPCR)  $\geq 0.75\text{g/g}$  **AND**;
6. One of the following applies:
  - a. Patient is taking an angiotensin converting enzyme inhibitor (ACEI) or angiotensin II receptor blocker (ARB) at maximally tolerated dose for a minimum of 90 days and will continue to do so while taking Voyxact<sup>®</sup>
  - b. Patient has a documented clinical contraindication or prior adverse reaction to both ACEI and ARBs.

**DENIAL CRITERIA<sup>1</sup>**

1. Failure to meet approval criteria **OR**;
2. Patient is currently receiving a systemic immunosuppressant **OR**;
3. Patient has a significant, active infection

**CAUTIONS<sup>1</sup>**

- Due to immunosuppression, Voyxact<sup>®</sup> can increase the risk of infection. Patients should be monitored for signs and symptoms of infection while undergoing treatment.
- Live vaccines are not recommended within 30 days of treatment initiation or while currently taking Voyxact<sup>®</sup>.
- The most common adverse reactions include upper respiratory tract infection and injection site erythema.

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**DURATION OF APPROVAL**

- Initial Approval: up to 6 months
- Reauthorization Approval: up to 12 months

**QUANTITY LIMIT**

- One 400mg/2ml syringe every 28 days

**REFERENCES / FOOTNOTES:**

1. Voyxact (sibeprenlimab-szsi) [prescribing information]. Rockville, MD: Otsuka; November 2025
2. Perkovic V, Trimarchi H, Tesar V, et al. Sibeprenlimab in IgA nephropathy – interim analysis of a phase 3 trial. *N Engl J Med.* 2026;394:635-646.
3. Floege J, Barratt J, Cook HT, et al. Executive summary of the KDIGO 2025 clinical practice guideline for the management of immunoglobulin A nephropathy (IgAN) and immunoglobulin A vasculitis (IgAV). *Kidney Int.* 2025;108(4):548-554.
4. Institute for Clinical and Economic Review: B-Cell Directed Therapies for IgA Nephropathy: Final Policy Recommendations. March 31, 2026.