MEDICATION POLICY:
Voyxact® (sibeprenlimab-szsi)

Generic Name: Sibeprenlimab-szsi

Therapeutic Class or Brand Name: Voyxact®

Applicable Drugs: NA

Preferred: NA

Non-preferred: NA

Date of Origin: 5/5/2026

Date Last Reviewed / Revised: NA

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I through VIII are met)

I. Documented diagnosis of primary immunoglobulin A nephropathy by kidney biopsy

II. Documented rapid kidney function loss with urine protein-to-creatinine ratio (UPCR) ≥ 0.75 g/g OR urine protein ≥ 0.5 g/day

III. Documented eGFR ≥ 30 ml/min

IV. Documented treatment failure, contraindication, or intolerance to one or more drugs from ALL of the following medication classes in the prior 12 weeks

   A. Max or maximally tolerated ACE inhibitor or ARB

   B. Sodium-glucose co-transporter-2 inhibitor

   C. Glucocorticoid (e.g., methylprednisolone, prednisone)

V. Minimum age requirement: 18 years of age

VI. The medication is prescribed by or in consultation with a nephrologist

VII. Request is for a medication with the appropriate FDA labeling, or its use is supported by current clinical practice guidelines.

VIII. Refer to plan document for the list of preferred products. If requested agent is not listed as a preferred product, must have a documented failure, intolerance, or contraindication to a preferred product(s).

EXCLUSION CRITERIA

- May not be used in combination with Filspari (sparsentan), Vanrafia (atrasentan)
- Nephrotic syndrome
- Chronic infectious disease or acute infectious disease

OTHER CRITERIA

- Click or tap here to enter text.

Quantity / Days Supply Restrictions

- 400 mg/2ml – 1 syringe every 28 days

Approval Length

- **Authorization:** 6 months
- **Re-Authorization:** 6 months with an updated letter of medical necessity or progress notes showing improvement or maintenance with medication ie. egfr remains ≥30 ml/min/1.73 m2, and response as determined by provider in reduction in proteinuria from baseline

Appendix

Click or tap here to enter text.

References

1. Voyxact Package insert. Otsuka America Pharmaceutical, Inc.; 2025. Accessed May 5, 2026. label
2. Perkovic V, Trimarchi H, Tesar V, et al. VISIONARY Trial Investigators Group. Sibeprenlimab in IgA Nephropathy - Interim Analysis of a Phase 3 Trial. N Engl J Med. 2026 Feb 12;394(7):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.