

# PRIOR AUTHORIZATION CHECKLIST



## When an insurer requests a Prior Authorization (PA)

before approving coverage for a prescription, it is the responsibility of the healthcare provider to prepare and submit it. PA requirements vary among healthcare insurers. A specific PA form may be required by certain insurers.

Otsuka Patient Services can assist patients by conducting a benefits investigation, which will determine whether a PA is required and what the criteria are for coverage

To learn more, visit [VOYXACThcp.com](http://VOYXACThcp.com)

## When submitting a PA, the following information may be required:

### Patient Information

- Name
- Address (Not a PO box)
- Date of birth (MM/DD/YYYY)

### Insurance Information

- Policyholder Plan name
- Plan address
- BIN/PCN
- ID Number
- Rx Group Number
- Copy of front and back of the insurance card
- Completed and signed Prior Authorization form

### Healthcare Provider Information

- Name
- Tax ID number
- Specialty
- Office address
- Phone/fax number
- NPI number

### Requested Medical Information

- VOYXACT® (sibeprenlimab-szsi) Injection 400 mg/2 mL Prefilled Syringe.  \_\_\_\_\_ refills
- VOYXACT is injected subcutaneously once every 4 weeks

### Clinical Documentation

- Confirmed diagnosis of primary IgAN (biopsy report)**
- Lab reports, including uPCR or proteinuria and eGFR
- Current and previous IgAN therapies in the past 12 months (ACE inhibitor/ARB, GC, SGLT2 inhibitor, or other IgAN-indicated therapies)
- Intolerance or contraindications to any current formulary therapies (step therapy requirements)
- Consider a Letter of Medical Necessity or a Formulary Exception Letter
- New request**
- Continuation of therapy request\*
- \*If yes, specify how this medication was started:**
  - Previous prior authorization
  - Paid under another insurance
  - Recent hospital discharge
  - Other
- Any additional relevant clinical information

### Please check your documentation to avoid potential denials.

As a healthcare provider, you are responsible for submitting information directly to insurers. Potential reasons for denial may include:

- ✓ Incorrect ICD-10-CM code(s)
- ✓ Lack of clinical documentation supporting diagnosis

### Need assistance?

**Call 1-833-VOYXACT (833-869-9228)  
Monday–Friday, 8 AM–8 PM ET  
(except holidays)**

ACE=angiotensin-converting enzyme; ARB=angiotensin receptor blocker; GC=glucocorticoid; IgAN=immunoglobulin A nephropathy; SGLT2=sodium-glucose cotransporter 2.

The information contained in this document is provided for informational purposes by Otsuka Pharmaceutical America, Inc., for patients who have been prescribed VOYXACT. Accurate completion of reimbursement, or coverage-related documentation, is the responsibility of the healthcare provider and patient.

**Please see full [Important Safety Information](#) and [FULL PRESCRIBING INFORMATION](#) and [PATIENT INFORMATION](#).**

## INDICATION

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.

## IMPORTANT SAFETY INFORMATION

### CONTRAINDICATION

VOYXACT is contraindicated in patients with serious hypersensitivity to sibeprenlimab-szsi or any of the excipients of VOYXACT.

### WARNINGS AND PRECAUTIONS

**Immunosuppression and Increased Risk of Infections:** VOYXACT suppresses the immune system by reducing antibody production, which may increase the risk of infections. Patients with chronic or recurring infections may have an increased risk of serious infection. In clinical trials, infections occurred in 49% of patients treated with VOYXACT compared with 45% of patients treated with placebo.

Before initiating VOYXACT, assess patients for active infections. During treatment, monitor patients for signs and symptoms of infection. If a serious infection develops, consider interrupting VOYXACT until the infection is controlled.

**Immunosuppression and Immunization Risks:** Because of its mechanism of action, VOYXACT may interfere with immune responses to vaccines and increase the risk of infection from live vaccines. Live vaccines are not recommended within 30 days prior to initiation of VOYXACT or during treatment with VOYXACT as safety has not been established. No data are available on the secondary transmission of infection from persons receiving live vaccines to patients receiving VOYXACT or on the efficacy of immunizations administered while receiving VOYXACT.

**Common Adverse Reactions:** The most common adverse reactions (reported in  $\geq 10\%$  of patients treated with VOYXACT and at a higher incidence than placebo) in patients treated with VOYXACT and placebo, respectively, were infections (49% versus 45%) and injection site reactions (24% versus 23%). The most common infection was upper respiratory infection (15% versus 14%), and the most common injection site reaction was injection site erythema (13% versus 12%). Most adverse reactions were reported as mild or moderate in severity and resolved without treatment interruption or discontinuation.

**Pregnancy:** There are no available data on VOYXACT use in pregnant women to evaluate for a drug-associated risk of major birth defects, miscarriage or other adverse maternal or fetal outcomes. Monoclonal antibodies, such as sibeprenlimab-szsi, can be actively transported across the placenta as pregnancy progresses; therefore, potential effects on a fetus are likely to be greater during the second and third trimester of pregnancy.

**Lactation:** There are no data on the presence of sibeprenlimab-szsi in human milk, the effects of sibeprenlimab-szsi on the breastfed infant, or the effects of sibeprenlimab-szsi on milk production.

**Pediatric Use:** Safety and effectiveness of VOYXACT in pediatric patients have not been established.

**Geriatric Use:** Clinical studies of VOYXACT did not include sufficient numbers of patients aged 65 and over to determine whether they respond differently from younger adult patients.

Pregnant women exposed to VOYXACT, or their healthcare providers, should report VOYXACT exposure by calling **1-833-869-9228** or visiting [www.VOYXACT.com](http://www.VOYXACT.com)

To report SUSPECTED ADVERSE REACTIONS, contact Otsuka America Pharmaceutical, Inc. at **1-800-438-9927** or FDA at **1-800-FDA-1088** ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)).

**Please see FULL PRESCRIBING INFORMATION and PATIENT INFORMATION.**

**References:** **1.** Centers for Disease Control and Prevention. ICD-10-CM. April 1, 2025. Accessed September 9, 2025. <https://icd10cmtool.cdc.gov/?fy=FY2024> **2.** American Medical Association. ICD-10. Accessed September 9, 2025. <https://www.ama-assn.org/topics/icd-10> **3.** Drugs.com. National Drug Codes Explained. March 20, 2025. Accessed September 11, 2025. <https://www.drugs.com/ndc.html>