BILLING AND CODING INFORMATION

Voyxact® (sibeprenlimab-szsi) Injection 400 mg/2 mL

Otsuka™ Patient Services

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for VOYXACT®. Coding and coverage policies change periodically and often without warning. The codes shown here are only general suggestions and are not intended to encourage or suggest a use of any drug that is inconsistent with FDA-approved use. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of his/her own patients. The information provided in this document should not be considered a guarantee of coverage or reimbursement for VOYXACT.

The content below describes the types of codes that are likely to be most relevant to claims for VOYXACT. VOYXACT is an injection for adult subcutaneous self-administration at home.

International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) Diagnosis Codes[1,2]

ICD-10-CM diagnosis codes are used for identifying and documenting a patient's specific diagnosis. These codes are used by all healthcare providers. Local coverage determinations and articles should be consulted for additional covered indications.

Code	Description
N02.B	Recurrent and persistent IgA nephropathy
N02.B1	Recurrent and persistent IgA nephropathy with glomerular lesion
N02.B2	Recurrent and persistent IgA nephropathy with focal and segmental glomerular lesion
N02.B3	Recurrent and persistent IgA nephropathy with diffuse membranoproliferative glomerulonephritis
N02.B4	Recurrent and persistent IgA nephropathy with diffuse membranous glomerulonephritis
N02.B5	Recurrent and persistent IgA nephropathy with diffuse mesangial proliferative glomerulonephritis
N02.B6	Recurrent and persistent IgA nephropathy with diffuse mesangiocapillary glomerulonephritis
N02.B9	Other recurrent and persistent IgA nephropathy

IgA=immunoglobulin A.

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National Drug Codes (NDC)[3]

An NDC is a unique, 3-segment number that serves as a universal product identifier for a drug.

NDCs	**10-digit code: 59148-400-75** **11-digit code: 59148-0400-75**
Description	Prefilled syringe (pack of 1)
Concentration	400 mg/2 mL

Electronic data exchange standards usually require the use of an 11-digit NDC. To convert a 10-digit NDC to an 11-digit NDC, a leading zero is added within the sequence of numbers.[3] Some payers may require each NDC to be listed on the claim. Payer requirements regarding the use of NDCs may vary.

Our Team Is Committed to You and Your Patients

Otsuka's support doesn't end once a prescription is submitted. Your office will also have access to a Field Reimbursement Manager who can assist with:

- Access and reimbursement questions
- Prior authorizations, letters of medical necessity, and appeals

If you have any questions or would like to speak to a Field Reimbursement Manager, please reach out to **Otsuka Patient Services.**

VOYXACT Prescriptions Are Filled Through PANTHERx Rare Specialty Pharmacy

Upon receipt of a prescription, PANTHERx Rare coordinates VOYXACT delivery directly with your patient.

PANTHERx RARE

Otsuka Patient Services Helpdesk:

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

Fax: **1-877-875-1264**

E-prescribe: **PANTHERx Rare NPI 1750843314**

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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 ≥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

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).

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

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