

VOYXACT® (sibeprenlimab-szsi) Prescription Start Form for VA Patients

Forward completed form to the VA pharmacy.
The VA pharmacy will fax completed form to PANTHERx Rare Pharmacy.
PANTHERx Rare | Phone: 1-833-869-9228 | Fax: 1-877-875-1264

Confidential - Protected Health Information
Unique Entity ID (UEI) - EG8MFV1BJ9H6

*=required

1) Patient Information

First Name* _____ Last Name* _____ MI _____
Sex: M F Preferred Language _____ DOB* _____
Shipping Address* _____
City* _____ State* _____ ZIP* _____
Phone* _____ Mobile _____
Standard mobile carrier rates for voice and text messaging apply.

2) Shipping Information

Ship to: VA Pharmacy Patient Address

3) VA Pharmacy Information

VA Name* _____	DEA #** _____
Address* _____	Payment Method: <input type="checkbox"/> Credit Card (call purchasing contact) <input type="checkbox"/> E-invoice Tungsten Network
City* _____ State* _____ ZIP* _____	Purchase Order #* _____
Primary Purchasing Contact* _____	Secondary Purchasing Contact _____
Phone* _____ Fax* _____	Phone _____ Fax _____
Email* _____	Email _____
Primary Clinical Contact* _____	Secondary Clinical Contact _____
Phone* _____ Fax* _____	Phone _____ Fax _____
Email* _____	Email _____

4) Prescriber Information

Specialty: Nephrology Internal Medicine Other _____
Prescriber Name* _____ Hospital/Clinic Name* _____
Address* _____
City* _____ State* _____ ZIP* _____
Office Contact* _____ Phone* _____ Fax* _____
NPI #** _____ State License #* _____

5) Prescription Information

ICD-10 Code:* **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) Other: _____
Clinical Background:
Kidney Biopsy* Yes No Date of Kidney Biopsy* _____ eGFR* _____ Proteinuria/uPCR* _____
Current/Previous IgA Nephropathy Therapies* _____

Dosing: Dispense VOYXACT 400 mg/2 mL prefilled syringe, subcutaneous injection administered once every 4 weeks NDC: 59148-400-75 12 refills, OR _____ refills

Rx Date _____ Rx Needed By Date _____
Known Food/Drug Allergies _____ Prescriber Name* _____
 Brand Medically Necessary/Dispense as Written/Do Not Substitute May Substitute/Substitution Permissible

6) Prescriber Signature

I certify that therapy with VOYXACT is medically necessary for this patient based on my best professional judgment, and I have reviewed the current Prescribing Information for the prescribed product. I certify that the information provided in this form is complete and accurate to the best of my knowledge and medical expertise. I understand that I may not delegate signature authority. I attest that I am not on the HHS/OIG list of Excluded Individuals.

Prescriber Signature* (no stamps) _____ Date* _____

Please see [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

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**.

