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

Otsuka™ Patient Services

PRESCRIPTION START FORM

FOR VETERANS AFFAIRS/DEPARTMENT OF DEFENSE USE ONLY

From VOYXACT Prescription to Treatment: Guiding the Way

This form serves as a prescription for VOYXACT® and marks the first step in starting the process to request and receive treatment.

VOYXACT Start Form Steps

1. Fill out all required fields in the START form below and also make sure to include clinic notes and a copy of the insurance card (front and back).
2. Submit by fax to **1-877-875-1264** or e-prescribe to PANTHERx Rare NPI 1750843314.
3. The prescription will be processed and delivered through a specialty pharmacy to the patient's address listed on the form.

Support Is Available

If you have questions or need support, you can contact your dedicated Field Reimbursement Team or contact **Otsuka Patient Services** Helpdesk (Monday–Friday, 8 AM–8 PM ET, except holidays).

- ✔ Phone: **1-833-VOYXACT (833-869-9228)**
- ✔ Fax: **1-877-875-1264**
- ✔ E-prescribe to PANTHERx Rare NPI 1750843314

We're here to support you. Scan to learn more.
VOYXACThcp.com

Please see Important Safety Information and FULL PRESCRIBING INFORMATION and PATIENT INFORMATION.

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For questions or assistance (Mon–Fri, 8 AM–8 PM ET):
1-833-VOYXACT (869-9228) Fax: 1-877-875-1264
*Required fields.

1 Patient Information

*First Name

*Last Name

*Date of Birth (MM/DD/YYYY) ____ /____ /_____

Sex: ☐ Male ☐ Female ☐ Other

( ) ☐ Mobile ☐ Home

*Phone Number†

*OK to leave voicemails about VOYXACT?† ☐ Yes ☐ No

*Preferred Communication: ☐ Phone ☐ Email

Best Time to Contact: ☐ AM ☐ PM

Preferred Language (if not English): _____

*Address (Not a PO Box)

*City *State *ZIP Email

I give permission to the following care partner to discuss my personal health information (Optional):

☐ Mobile ☐ Home

Care Partner Contact Name Relationship to Patient Phone Number†

2 Patient Consent to Enroll

☐ **Sign up for Otsuka Patient Services.** I understand that agreeing to these services on pages 5 is voluntary and that I do not need to sign up to receive treatment from my healthcare provider. I understand that a signed copy of this consent is available upon request. Such services may include but are not limited to the following:

- Help coordinate insurance coverage for, access to, and receipt of my medication
- Communicate with me about possible financial assistance, and, if I am eligible, enroll and administer my participation in those programs
- Communicate with me about my medication, treatment, and disease, including reminders, and other product-related information
- Ask for feedback related to the services or my treatment experience

☐ **Get access to VOYXACT educational communications. I'd like to sign up for ongoing support where I will get VOYXACT tips, resources, and reminders from Otsuka at the email address I provided above.** By checking this box, I agree to receive recurring marketing communications regarding educational events, information, and services from VOYXACT. I understand that the information I have provided will be used by Otsuka America Pharmaceutical, Inc. ("Otsuka") and its contracted service providers to contact me by email, phone, or mail with relevant information. I will have the ability to opt out from receiving Otsuka communications at any time by calling **1-833-VOYXACT (869-9228)** or by following the opt-out instruction within the communications. For additional information, see Otsuka America Pharmaceutical Privacy Policy at: https://www.otsuka-us.com/oapi-and-opdc-privacy-policy.

Patient signature _____ *Date (MM/DD/YYYY)

3 *Pharmacy Information

*VA Name

*Address

*City *State *ZIP

*Payment Method: ☐ Credit card (call purchasing contact) ☐ E-invoice Tungsten Network

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HIPAA Authorization

I authorize PANTHERx Rare, my healthcare provider, and their business associates as necessary to disclose my Protected Health Information (PHI) as that term is defined under HIPAA, including PHI relating to my insurance benefits, medical condition, treatment, and prescription details to Otsuka and its affiliates, business partners, vendors, and other agents (Otsuka) so they can provide me with patient support services (the "Services") for which I am eligible. Once I authorize disclosure of my PHI, it may no longer be protected by federal health privacy law and applicable state laws.

I understand that PANTHERx Rare may receive payment from the Program for providing the Services outlined in this authorization.

My PHI includes:

- My name, address, and contact information provided on this form
- Any additional information about me, my treatment and health conditions, as provided by my doctor in order to enroll me in the Otsuka Patient Services program, and any other health information that my doctor may share with Otsuka in order for me to receive the patient support services
- Payer-related information received from my health insurer
- Prescription, fulfillment, shipment, and other information provided by pharmacies or other sites of care

I understand and agree that Otsuka may combine PHI collected from me with information about me collected from other sources and use that combined information to administer the Services. Otsuka may tokenize, aggregate, and de-identify my PHI and combine that de-identified PHI with other information, as long as the combined data remains de-identified in accordance with HIPAA standards (ie, an expert has opined that it cannot be used to identify me).

This HIPAA Authorization will expire 5 years after I sign it, unless I withdraw or cancel it sooner. If I cancel this HIPAA authorization, I may no longer qualify for Services from Otsuka, but it will not impact my Provider's treatment or my insurance benefits. I understand that this will not affect any uses or disclosures Otsuka has already acted in reliance on this authorization prior to the date this cancellation is received.

I understand that I do not have to sign this HIPAA Authorization to get my medication or insurance coverage, that I have a right to a copy, and that I can cancel this Authorization at any time by writing to:
PANTHERx Rare Specialty LLC, 121 Bayer Road, Building 5, Pittsburgh, PA 15205.

Patient signature _____ _____

***Date** *(MM/DD/YYYY)*

_____ ____ /____ /_____

***Patient Name** ***Patient Date of Birth** *(MM/DD/YYYY)*

5 *Pharmacy Information

*DEA Number

*Purchase Order Number

*Primary Purchasing Contact

Secondary Purchasing Contact

*Phone Number

*Fax Number

Phone Number

Fax Number

*Email

Email

*Primary Clinical Contact

Secondary Clinical Contact

*Phone Number

*Fax Number

Phone Number

Fax Number

*Email

Email

6 Prescriber Information

*Specialty: ☐ Nephrology ☐ Internal Medicine ☐ Other:

*Prescriber Name

*Hospital/Clinic Name

*Address

*City

*State

*ZIP

*Office Contact

*Phone Number

*Fax Number

*NPI Number

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For questions or assistance (Mon–Fri, 8 AM–8 PM ET):
1-833-VOYXACT (869-9228) Fax: 1-877-875-1264

*Required fields.

_____ ____/____/_____
***Patient Name** ***Patient Date of Birth** *(MM/DD/YYYY)*

7 Primary Diagnosis Code & Clinical Information

***Select an appropriate diagnosis code:**

☐ N02.B _____ Recurrent and persistent IgA nephropathy (IgAN)

☐ Other: _____

***Has the patient had a kidney biopsy?** ☐ Yes ☐ No **If yes, date of kidney biopsy or write N/A:** _____

***uPCR (g/g) or proteinuria (g/day) or write N/A:** _____

***eGFR (mL/min/1.73m²) or write N/A:** _____

***Please list the patient's current and previous IgAN treatment(s) and dates** *(MM/DD/YYYY)*:

_____

***Is there any reason the patient was not a candidate for specific treatments for IgAN?** (if applicable):

_____

***Known drug allergies:**

☐ Yes If yes, please list medication(s) and associated reaction(s): _____
☐ No known drug allergies

8 *Prescription Information

Please submit prescriptions by eScript if mandated by individual state laws. The prescriber must comply with state laws regarding e-prescribing, state-specific prescription form, or written prescription. Provide eScript to PANTHERx Rare by searching NPI 1750843314.

☐ **Dispense VOYXACT 400 mg/2 mL Prefilled Syringe: Injected subcutaneously once every 4 weeks.**

☐ **11 refills, or** _____ **refills**

9 *Prescriber Authorization

I certify that I am the healthcare professional who has prescribed the therapy identified in this form. I further certify that I have made an independent judgment that the above therapy is medically necessary, and that the information provided in this form is accurate to the best of my knowledge. I attest that I am not on the HHS/OIG List of Excluded Individuals and Entities and that I am presently authorized under state law to prescribe this medication. I authorize Otsuka, and its affiliates, agents, representatives, and service providers, to act on my behalf for the purposes of transmitting this prescription to the appropriate pharmacy.

***Prescriber signature required** _____ _____
***Date** *(MM/DD/YYYY)*

Please see Important Safety Information and FULL PRESCRIBING INFORMATION and PATIENT INFORMATION.

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Patient Consent to Otsuka Patient Services program

I consent to enrolling in the Otsuka Patient Services program. I hereby authorize Otsuka and its affiliates, business partners, vendors and other agents (collectively, "Otsuka"), to provide me with the patient support services for which I am eligible under this program. Such services may include but are not limited to assistance in obtaining approval for my prescription from my health insurance plan, emails relating to my prescription medication, including refill reminders, copay assistance if I am eligible, information about other financial assistance support, and other support services offered now or in the future. As part of the program's offerings, I agree to my enrollment in the assistance program if I am eligible.

I agree that Otsuka may send me information about the program, including disease state and medical education materials, via email to the email address I provided, even though email is not a secure method for transmission of confidential personal information. I acknowledge and agree that Otsuka may process my personal information in accordance with its privacy policy, which is found here: https://www.otsuka-us.com/privacy-policy.

I hereby expressly consent to the processing of my sensitive health information by Otsuka as necessary in order to provide me with the patient support services.

I understand that Otsuka Patient Services may use and share with my healthcare providers, pharmacies, and health insurance plans, my sensitive personal information in order to provide me with services under the program, administering the program, or as otherwise required for Otsuka to meet its legal obligations.

I understand that I may be requested to provide my written consent on an annual basis by the Otsuka Patient Services program in order to continue to provide me with patient support. I understand that my pharmacy may receive payment from the program for providing the support services outlined in this consent as authorized in this consent.

I understand that I have the ability to opt out from receiving Otsuka communications at any time by calling **1-833-VOYXACT (869-9228)** or by following the opt-out instruction within the communications. For additional information, see Otsuka America Pharmaceutical Privacy Policy at: https://www.otsuka-us.com/oapi-and-opdc-privacy-policy.

By signing the Consent Form on page 2, I agree that Otsuka may contact my caregiver listed on the form and share my sensitive health information with my caregiver for the purpose of providing me with the patient support services.

†**Otsuka Patient Services may call you at the numbers provided for nonmarketing purposes** (eg, to help you access and start on VOYXACT). Calls may be autodialed. You may change your preferences at any time by calling **1-833-VOYXACT (833-869-9228).**

For questions or assistance (Mon–Fri, 8 AM–8 PM ET):
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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.

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