Patient Consent Form

Patient Authorization

By signing below, I am enrolling in the Otsuka Patient Support program. I authorize Otsuka and its affiliates, business partners, vendors and other agents to provide me with services for which I am eligible under this program. Such services may include medication and adherence communications and support, medication dispensing support, insurance coverage and financial assistance support, disease and medication education, 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 understand that to be eligible for commercial copay assistance I must have commercial insurance that covers medication costs and not be enrolled in federal or state subsidized healthcare programs that cover prescription drugs, including Medicare, Medicaid, TRICARE, or any other federal or state healthcare plan, including state pharmaceutical assistance programs. I understand and agree that a benefit verification will be performed and commercial copay savings assistance will not be provided if eligibility cannot be verified.

Patient Name _____ DOB _____

Signature of Patient _____ Date _____

Legal Representative Name _____ Legal Representative Signature _____

If signed by patient legal representative, provide authority to sign on behalf of the patient.

I understand that Otsuka and its business partners may use and share with each other and with my healthcare providers, pharmacies, and health insurance plans, my information in connection with providing services to me under the program, administering the program, or as otherwise required for Otsuka to meet its legal obligations.

I authorize that my PHI may be sent to Otsuka Patient Support by my healthcare provider and pharmacy, disclosed to and reviewed by Otsuka and its authorized representatives and vendors of Otsuka, including Otsuka Patient Support call center staff, as necessary to provide the support available, including transition of care support. This includes sending my PHI as provided by my healthcare provider and pharmacy to my health insurers, pharmacies, advocacy organizations, and third parties such as data aggregators, copay card vendors, laboratories, safety program administrators, patient access centers, and the patient assistance program pharmacy. There is a potential for the information to be subject to re-disclosure by the recipient and no longer protected by HIPAA.

My PHI may include:

- information provided on this form
- healthcare records related to my treatment and health condition(s)
- payer-related information received from my health insurer
- prescription, fulfillment, shipment, and other information provided by pharmacies or other sites of care
- information to help support my transition of care

My authorization and notice of release will remain in effect for one (1) year from the date of my signature. I understand that I may be requested to provide my written consent on a biannual basis by the program in an effort to support continued access to prescribed treatment. 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. Signing this consent form is voluntary. I understand that I can refuse to sign this form and it will not affect the start, continuation, or quality of my treatment from my healthcare provider.

After I have signed this consent, I may withdraw it by calling Otsuka Patient Support at **888-564-9611** or by sending a written notice to **Patient Consent Management, PO Box 61204, King Of Prussia, PA 19406 with the following information:**

- Authorization Revocation, Patient First Name, Patient Last Name, Patient Date of Birth, Contact Phone Number, Contact Address

The withdrawal goes into effect once it has been received and will not affect the information that had been sent or obtained prior to the date of withdrawal. If I choose to not sign this authorization or I withdraw it after signing this form, Otsuka Patient Support will not be able to provide me with the support described above after the date of my revocation. I understand that if I withdraw, it will not have any effect on any uses or disclosure of my information that occurred prior to receiving my withdrawal.

Information about the Otsuka privacy policy and information about your rights concerning your data, can be found at otsuka-us.com/oapi-and-opdc-privacy-policy.

☐ *By completing the contact information on the right, the patient agrees that protected health information may be shared with the person named on the right.*

Caregiver/ alternate Contact Name _____ Relationship _____

Phone _____ Mobile _____

Standard mobile carrier rates for voice and text messaging apply.

Patient Name _____ DOB _____

Signature of Patient _____ Date _____

Legal Representative Name _____ Legal Representative Signature _____

If signed by legal representative, indicate the relationship to the patient and your authority to act for the patient.

☐ **AllianceRx Walgreens Prime**
alliancerxwp.com
130 Enterprise Drive,
Pittsburgh, PA 15275
Phone: (800) 480-9052
Fax: (877) 231-8302
Hours (EST): **M-F:** 8AM-7PM,
SAT: 9AM-3PM, **SUN:** Closed
NPI: 1972560688

☐ **Optum (Avella)**
avella.com
24416 N 19th Avenue,
Phoenix, AZ 85085
Phone: (877) 719-6330
Fax: (877) 546-5780
Hours (EST): **M-F:** 6AM-6PM,
SAT: 9:30AM-12:30PM, **SUN:** Closed
NPI: 1780030163

☐ **PANTHERxRare**
pantherxrare.com
24 Summit Park Drive,
Pittsburgh, PA 15275
Phone: (833) 599-2245
Fax: (855) 246-3986
Hours (EST): **M-F:** 8AM-8PM,
SAT: 9AM-3PM, **SUN:** Closed
NPI: 1316213531

Otsuka
Otsuka America Pharmaceutical, Inc.

Prescription Referral Form

Confidential - Protected Health Information
*=required.

1) Patient Demographic Information

First Name* Last Name* MI DOB*

Address

City State: ZIP

Gender: ☐M / F☐ Preferred Language Email

Phone* ( ) - Mobile ( ) -

Please attach a copy of your patient's current insurance card as well as an updated medication list.

Standard mobile carrier rates for voice and text messaging apply.

2) Prescription Information

ICD-10 code:* ☐ Q61.2 *(autosomal dominant polycystic kidney disease)* ☐ Other:

Prescription:* *Please note Specialty Pharmacy may dispense no more than 4 weekly blister packs at a time.*

☐ 45-mg/15-mg JYNARQUE® (tolvaptan) tablets, b.i.d., take one 45-mg tablet p.o. upon waking, one 15-mg tablet p.o. 8 hours later.

☐ 4 weekly blister packs ☐ 3 weekly blister packs ☐ 2 weekly blister packs ☐ 1 weekly blister pack ☐ Refills ___

☐ 60-mg/30-mg JYNARQUE® (tolvaptan) tablets, b.i.d., take one 60-mg tablet p.o. upon waking, one 30-mg tablet p.o. 8 hours later.

☐ 4 weekly blister packs ☐ 3 weekly blister packs ☐ 2 weekly blister packs ☐ 1 weekly blister pack ☐ Refills ___

☐ 90-mg/30-mg JYNARQUE® (tolvaptan) tablets, b.i.d., take one 90-mg tablet p.o. upon waking, one 30-mg tablet p.o. 8 hours later.

☐ 4 weekly blister packs ☐ 3 weekly blister packs ☐ 2 weekly blister packs ☐ 1 weekly blister pack ☐ Refills ___

Dose reduction of JYNARQUE is recommended for patients while taking moderate CYP3A inhibitors *(see Dosage and Administration [2.4])*. Patients should avoid grapefruit juice beverages while taking JYNARQUE.

Other Dosages Available:

☐ 15-mg/15-mg JYNARQUE® (tolvaptan) tablets, b.i.d., take one 15-mg tablet p.o. upon waking, one 15-mg tablet p.o. 8 hours later.

☐ 4 weekly blister packs ☐ 3 weekly blister packs ☐ 2 weekly blister packs ☐ 1 weekly blister pack ☐ Refills ___

☐ 30-mg/15-mg JYNARQUE® (tolvaptan) tablets, b.i.d., take one 30-mg tablet p.o. upon waking, one 15-mg tablet p.o. 8 hours later.

☐ 4 weekly blister packs ☐ 3 weekly blister packs ☐ 2 weekly blister packs ☐ 1 weekly blister pack ☐ Refills ___

1 weekly blister pack, 7-day supply, 14 tablets, 2 weekly blister packs, 14-day supply, 28 tablets, 3 weekly blister packs, 21-day supply, 42 tablets, 4 weekly blister packs, 28-day supply, 56 tablets

Titration Directions (if needed)

Special Instructions

Known Food/Drug Allergies

Rx Date* NPI #* Prescriber Name*

Prescriber Signature*

Brand Medically Necessary/Dispense as Written/Do Not Substitute

Prescriber's signature required (NO STAMPS).

Prescriber Authorization:

☐ Yes ☐ No I certify that therapy with JYNARQUE® (tolvaptan) 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 and that I am presently authorized under State law to prescribe and dispense the requested medication.

☐ Yes ☐ No If the patient insurance plan allows the pharmacy to submit an authorization request on behalf of prescriber, I authorize the Specialty Pharmacy and its representatives to act as my authorized agent to secure coverage and initiate the insurance prior authorization for process for this patient, including the signing of any required forms on my behalf as my authorized agent.

Prescriber Signature* Date*

Prescriber's signature required (NO STAMPS).

First Name* Last Name* MI

State License #* DEA #

Site Name and Address

City* State* ZIP*

Phone* ( ) - Fax ( ) -

Required for SPs

Office Contact Name* (and contact information if different from above)

☐ **AllianceRx Walgreens Prime**
Phone: (800) 480-9052 Fax: (877) 231-8302

☐ **Optum (Avella)**
Phone: (877) 719-6330 Fax: (877) 546-5780

☐ **PANTHERxRare**
Phone: (833) 599-2245 Fax: (855) 246-3986

Please see **IMPORTANT SAFETY INFORMATION** on page 2.

INDICATION and IMPORTANT SAFETY INFORMATION for JYNARQUE® (tolvaptan)

INDICATION:

JYNARQUE is indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

IMPORTANT SAFETY INFORMATION:

WARNING: RISK OF SERIOUS LIVER INJURY

- **JYNARQUE (tolvaptan) can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported**
- **Measure transaminases (ALT, AST) and bilirubin before initiating treatment, at 2 weeks and 4 weeks after initiation, then monthly for the first 18 months and every 3 months thereafter. Prompt action in response to laboratory abnormalities, signs, or symptoms indicative of hepatic injury can mitigate, but not eliminate, the risk of serious hepatotoxicity.**
- **Because of the risks of serious liver injury, JYNARQUE is available only through a Risk Evaluation and Mitigation Strategy program called the JYNARQUE REMS Program**

CONTRAINDICATIONS:

- History, signs or symptoms of significant liver impairment or injury. This contraindication does not apply to uncomplicated polycystic liver disease
- Taking strong CYP3A inhibitors
- With uncorrected abnormal blood sodium concentrations
- Unable to sense or respond to thirst
- Hypovolemia
- Hypersensitivity (e.g., anaphylaxis, rash) to JYNARQUE or any component of the product
- Uncorrected urinary outflow obstruction
- Anuria

Serious Liver Injury: JYNARQUE can cause serious and potentially fatal liver injury. Acute liver failure requiring liver transplantation has been reported in the post-marketing ADPKD experience. Discontinuation in response to laboratory abnormalities or signs or symptoms of liver injury (such as fatigue, anorexia, nausea, right upper abdominal discomfort, vomiting, fever, rash, pruritus, icterus, dark urine or jaundice) can reduce the risk of severe hepatotoxicity. To reduce the risk of significant or irreversible liver injury, assess ALT, AST and bilirubin prior to initiating JYNARQUE, at 2 weeks and 4 weeks after initiation, then monthly for 18 months and every 3 months thereafter.

Hypernatremia, Dehydration and Hypovolemia: JYNARQUE therapy increases free water clearance which can lead to dehydration, hypovolemia and hypernatremia. Instruct patients to drink water when thirsty, and throughout the day and night if awake. Monitor for weight loss, tachycardia and hypotension because they may signal dehydration. Ensure abnormalities in sodium concentrations are corrected before initiating therapy. If serum sodium increases above normal or the patient becomes hypovolemic or dehydrated and fluid intake cannot be increased, suspend JYNARQUE until serum sodium, hydration status and volume status parameters are within the normal range.

Inhibitors of CYP3A: Concomitant use of JYNARQUE with drugs that are moderate or strong CYP3A inhibitors (e.g., ketoconazole, itraconazole, lopinavir/ritonavir, indinavir/ritonavir, ritonavir, and conivaptan) increases tolvaptan exposure. Use with strong CYP3A inhibitors is contraindicated; dose reduction of JYNARQUE is recommended for patients taking moderate CYP3A inhibitors. Patients should avoid grapefruit juice beverages while taking JYNARQUE.

Adverse Reactions: Most common observed adverse reactions with JYNARQUE (incidence >10% and at least twice that for placebo) were thirst, polyuria, nocturia, pollakiuria and polydipsia.

Other Drug Interactions:

- **Strong CYP3A Inducers:** Co-administration with strong CYP3A inducers reduces exposure to JYNARQUE. Avoid concomitant use of JYNARQUE with strong CYP3A inducers
- **OATP1B1/3 and OAT3 Transporter Substrates:** Patients who take JYNARQUE should avoid concomitant use with OATP1B1/B3 and OAT3 substrates (e.g., statins, bosentan, glyburide, nateglinide, repaglinide, methotrexate, furosemide), as the plasma concentrations of these substrates may be increased
- **BCRP Transporter Substrates:** Tolvaptan is an inhibitor of BCRP. Patients who take JYNARQUE, should avoid concomitant use with BCRP substrates (e.g., rosuvastatin)
- **V_2-Receptor Agonist:** Tolvaptan interferes with the V_2-agonist activity of desmopressin (dDAVP). Avoid concomitant use of JYNARQUE with a V_2-agonist.

Pregnancy and Lactation: Based on animal data, JYNARQUE may cause fetal harm. In general, JYNARQUE should be discontinued during pregnancy. Advise women not to breastfeed during treatment with JYNARQUE.

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, including **BOXED WARNING**.

Otsuka

Otsuka America Pharmaceutical, Inc.

Manufactured by Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.
Distributed and marketed by Otsuka America Pharmaceutical, Inc., Rockville, MD 20850 USA.

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