MY PASS™

PERSONALIZED ADPKD SUPPORT SERVICE

Patient Consent Form and Prescription Referral Form

Did you...?

- ☐ Enroll as a provider in the JYNARQUE REMS Program (www.JYNARQUEREMS.com)
- ☐ Enroll the patient in the JYNARQUE REMS Program
- ☐ Obtain the patient signature on the Patient Consent Form (p 1/5)
- ☐ Complete the Prescription Referral Form (p 2/5 to 5/5)
- ☐ Send the fax coversheet and completed forms to the patient's preferred REMS-certified specialty pharmacy
- ☐ Call 1-833-J-MYPASS with any questions or visit www.j-mypass.com/prescribe to fill out online

REMS-certified specialty pharmacies

AllianceRx
alliancerxwp.com
130 Enterprise Drive, Pittsburgh, PA 15275
Phone: (800) 480-9052 | **Fax:** (877) 546-5780
Hours (EST):
SUN–SAT: 8AM–7PM

PANTHERx
pantherspecialty.com
24 Summit Park Drive, Pittsburgh, PA 15275
Phone: (833) 599-2245 | **Fax:** (412) 420-6242
Hours (EST):
M–F: 8AM–8PM, **SAT:** 9AM–3PM, **SUN:** Closed

Avella
avella.com
24416 N 19th Drive, Phoenix, AZ 85085
Phone: (877) 719-6330 | **Fax:** (877) 546-5780
Hours (MST):
M–F: 6AM–6PM, **SAT:** 9:30AM–12:30PM, **SUN:** Closed

Fax Cover Sheet

The pages that follow contain confidential, protected health information.

MY PASS
PERSONALIZED ADPKD SUPPORT SERVICE
Phone: 1-833-J-MYPASS

To:

From:

Subject:

Date: Time: Pages (including cover):

COMMENTS:

For patients leaving an Otsuka-sponsored clinical trial of tolvaptan for ADPKD *Complete only if it applies:*

☐ This patient is currently completing the end-of-study process for an Otsuka-sponsored clinical trial of tolvaptan for ADPKD.

Clinical Trial Site Name **Site #** **Study ID**

Changes in treating physician *Check any box that applies:*

☐ I am receiving this patient from another site of care.

☐ I am referring this patient to another site of care. If this is a referral, please complete below.

I WILL BE REFERRING THIS PATIENT TO THE SITE OF CARE LISTED BELOW:

Receiving HCP Name

Receiving Site Name

Phone ( ) - **Fax** ( ) -

City **State** **ZIP**

CONFIDENTIALITY NOTE

The documents accompanying this telecopy transmission contain confidential or privileged information. The information is intended for the use of the individual or entity named on this transmission sheet. If you are not the intended recipient, be aware that any disclosure, copying, distribution or use of the contents of this telecopied information is prohibited. If you have received this telecopy in error, please notify us by telephone immediately so that we can arrange for the retrieval of the original document at no cost to your office. Thank you for your assistance.

April 2018 10US18EBP0161

Patient Name _____ **DOB** _____

Patient Consent Form

MyPASS – My Personalized ADPKD Support Service™ (the "Program") is offered by Otsuka to help patients throughout their treatment with JYNARQUE™ (tolvaptan). The Program includes commercial copay savings, no-cost medication for a limited number of months while obtaining insurance coverage, and adherence support as key components.

Patients can benefit from prescription management, support in securing reimbursement, referrals to financial patient support programs, drug shipment, and refill outreach without enrolling.

Patient Authorization

MyPASS – I authorize the Program to contact me by phone, mail, or email and to provide support for my treatment with JYNARQUE, such as:

- laboratory testing and appointment reminders
- medication and refill reminders
- potential access to no-cost medication while insurance coverage is being determined

Copay Savings – I authorize MyPASS to apply Otsuka commercial copay savings assistance to my prescription.
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.

HIPAA Disclosure – I authorize that my protected health information (PHI) be shared with MyPASS and its partners.
I authorize that my PHI may be sent to the Program, disclosed to and reviewed by Otsuka and its authorized representatives and vendors of Otsuka working with the Program, including Program 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, laboratory, 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 two (2) years 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. 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 MyPASS at 1-833-J-MYPASS or by sending a written notice to My Personalized ADPKD Support Service™ c/o ASSURE Program™, Covance Market Access Services, PO Box 3040, Gaithersburg, MD 20885-3040. The withdrawal goes into effect once it has been received by the Program. If I choose to not sign this authorization or I withdraw it after signing this form, the Program will not be able to provide me with the support described above after the date of my revocation.

Patient Name _____ **DOB** _____

Signature of Patient _____ **Date** _____

Legal Representative Name _____ **Legal Representative Signature** _____

☐ **OPTIONAL communications from the maker of JYNARQUE**

Email: _____

I am interested in receiving information about additional offerings such as speaking opportunities, tools and resources to support my treatment, and educational materials about JYNARQUE™ (tolvaptan), including information about ADPKD or related events in my area. I understand I do not need to agree to this additional opt-in to be eligible to receive the program services outlined above.

Patient Name _____ **DOB** _____

Prescription Referral Form

*=required.

1) Pharmacy Selection

Has prescription information been sent to a REMS-certified specialty pharmacy already?* ☐ **Yes** ☐ **No**

Check name of selected or preferred REMS-certified specialty pharmacy below:*

Best attempt will be made to honor the pharmacy selected below. Please note that the health insurer may dictate a different preferred specialty pharmacy.

☐ **AllianceRx**
alliancerxwp.com
130 Enterprise Drive, Pittsburgh, PA 15275
Phone: (800) 480-9052 | **Fax:** (877) 546-5780
Hours (EST): SUN–SAT: 8AM–7PM

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

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Hours (EST): M–F: 8AM–8PM, **SAT:** 9AM–3PM, **SUN:** Closed

2) Patient Demographic Information

☐ **Check if copy of demographic/face sheet is attached. You must still fill in first name, last name, and DOB below.**

First Name* _____ **Last Name*** _____ **MI** _____

Address _____

City _____ **State:** _____ **ZIP** _____

SSN _____ **Gender:** M ☐ F ☐ **DOB*** _____

Preferred Language _____ **Email** _____

Phone ( ) - **Mobile** ( ) -

Standard mobile carrier rates for voice and text messaging apply.

☐ **Check if there is a primary caregiver or an alternate contact.**
By completing the contact information below, the patient agrees that protected health information may be shared with the person named below and that the person named below agrees to be contacted by the Program in reference to the patient.

Caregiver/alternate Contact Name _____ **Relationship** _____

Phone ( ) - **Mobile** ( ) -

Standard mobile carrier rates for voice and text messaging apply.

Patient Name _____ **DOB** _____

3) Patient Insurance Information

Check the box that applies:* *=required.

- ☐ Patient does not have insurance.
- ☐ Patient has insurance coverage. Copies of all medical and prescription insurance cards are attached.
- ☐ Patient has insurance coverage. Insurance information is provided in the section below:

PRIMARY INSURANCE

Prescription Card Member ID _____ BIN _____ PCN _____

Medical Card Payer Name _____ Plan Name _____

Member ID _____ Group # _____ Phone ( ) -

Policyholder Name _____ Policyholder DOB _____

SECONDARY INSURANCE

Prescription Card Member ID _____ BIN _____ PCN _____

Medical Card Payer Name _____ Plan Name _____

Member ID _____ Group # _____ Phone ( ) -

Policyholder Name _____ Policyholder DOB _____

4) Prescriber Information

Specialty: ☐ Nephrology ☐ Internal Medicine ☐ Other: _____

Site Type: ☐ Hospital/Institution ☐ Clinical/Private Practice ☐ Other: _____

Name* _____ Last Name* _____ MI _____

State License #* _____ NPI #* _____ DEA # _____

Site Name and Address _____

City* _____ State* _____ ZIP* _____

Prescriber Direct Phone* ( ) - Ext _____

Prescriber Mobile Phone ( ) - Prescriber Email* _____

Standard mobile carrier rates for voice and text messaging apply.

Please see **IMPORTANT SAFETY INFORMATION** on the last page of this document.

For additional assistance, please contact 1-833-J-MYPASS.

Patient Name _____ **DOB** _____

Prescriber Information (continued) *=required.

Contact Name (First and Last) _____

Contact Direct Phone ( ) - Ext _____

Contact Fax ( ) - Contact Email _____

Contact Mobile Phone ( ) - Preferred method of contact: ☐ Phone ☐ Mobile ☐ Fax ☐ Email

Standard mobile carrier rates for voice and text messaging apply.

5) Prescription Information

Patient Name* _____ DOB* _____

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

Prescription:*

☉ **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.

Disp # _____ tablets; _____ 7-day blister pack(s)

☐ **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.

Disp # _____ tablets; _____ 7-day blister pack(s)

☐ **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.

Disp # _____ tablets; _____ 7-day blister pack(s)

Special Instructions _____

Known Food/ Drug Allergies _____

Titration Directions (if needed) _____

Rx Date* _____ Refill* x _____ NPI #* _____

Prescriber Name* _____ **Prescriber's signature required (NO STAMPS).**

Prescriber Signature* _____ Prescriber Signature* _____

Brand Medically Necessary/Dispense as Written/Do Not Substitute *May Substitute/Substitution Permissible*

Please see **IMPORTANT SAFETY INFORMATION** on the last page of this document.

For additional assistance, please contact 1-833-J-MYPASS.

Patient Name **DOB**

***=required.**

6) Prescriber Authorization

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.

I also certify that I have obtained patient consent for the disclosure of protected health information (PHI) as required by the Health Insurance Portability and Accountability Act of 1996, as amended ("HIPAA"), and any other legally required consents of the patient (or the patient's legal representative) for the release of the patient's information to MyPASS (the "Program") and Otsuka or its representatives or agents, as may be necessary for the patient's participation in the Program, and for the Program and Otsuka to use and disclose such information as necessary to provide reimbursement support and other related information and resources to me and my patient in connection with the patient's therapy.

I understand that the Program and Otsuka will use and disclose this information only in connection with the Program, including but not limited to performing a benefit verification of the patient's insurance coverage for the prescribed treatment or triaging the patient's prescription to the patient's preferred pharmacy, as otherwise required or permitted by law.

I further certify that (a) any support provided through the Program on behalf of any patient is not given in exchange for any express or implied agreement or understanding that I would recommend, prescribe, or use any Otsuka product or service, and (b) my decision to prescribe the Otsuka product or service was based on my determination of medical necessity as set forth herein. I agree that the Program and Otsuka may contact me for additional information relating to the Program or Otsuka product, including but not limited to email, fax, and telephone. I understand that Otsuka reserves the right, at any time and without notice, to modify or discontinue the Program.

I understand that completing this enrollment form does not ensure that the patient will obtain insurance coverage or reimbursement for my prescription, and that any support provided through the Program is provided for informational purposes only and represents no statement, promise, or guarantee by the Program or Otsuka. I agree that in no event shall Otsuka be liable for any damages resulting from or relating to the Program.

Prescriber Signature* **Date***

Prescriber's signature required (NO STAMPS).

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.
JYNARQUE is a trademark of Otsuka Pharmaceutical Co., Ltd., Tokyo, 101-8535 Japan.

April 2018 10US18EBP0161