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Thank you for choosing PANTHERx. As a designated dispensing pharmacy for JYNARQUE® (tolvaptan), we are pleased to participate in your patients' healthcare. The following is a reference tool with suggested guidance for prescription submission.

PANTHERx is required by the FDA to verify REMS (Risk Evaluation and Mitigation Strategy) enrollment status for both prescriber and patient. PANTHERx will only receive FDA authorization to dispense the medication to your patient once this has been completed.

Please ensure you have carefully completed both forms in their entirety. If left incomplete, required fields marked with an (*) will delay the REMS enrollment process and result in additional outreaches to your office.

- Enrollment for the JYNARQUE REMS program is available online at www.jynarqueREMS.com OR via fax submission to the FDA 866-750-6820. Please complete the following 2 forms:
 1. REMS PRESCRIBER ENROLLMENT FORM
 2. REMS PATIENT ENROLLMENT FORM

The PANTHERx staff provides prior authorization and appeals management to assist with the needs of your office. We will initiate and submit the prior authorization request on your behalf, as permitted by the patient's PBM (pharmacy benefits manager).

Along with the completed prescription, please include copies the following documents to ensure a complete plan review:

- Signed OTSUKA PATIENT CONSENT FORM to opt-in for patient support offerings
- Recent Office Progress Note Including:
 - Documentation of Familial History
 - Current Stage of Chronic Kidney Disease (CKD)
 - Recent Estimated Glomerular Filtration Rate (eGFR)
 - Baseline Liver function testing (ALT, AST, Bilirubin)
 - For reference, the acceptable ICD-10 for ADPKD is Q61.2
 - Genetic Testing*
 - MRI/CT/Imaging Report*
- Current allergy and medication list
- Copy of active Pharmacy benefits

**If available; not required by all plans*

If patient is at risk for rapid progression, please also submit documentation to support:

- Enlarged Kidneys (>16.5cm)
- Recent Estimated Glomerular Filtration Rate (eGFR) decline of >5mL in 1 year
- Total Kidney Volume (TKV) increase of 5% demonstrated via imaging
- Hypertension prior to age 35