

AvMed

PHARMACY PRIOR AUTHORIZATION/STEP-EDIT REQUEST*

Directions: The prescribing physician must sign and clearly print name (preprinted stamps not valid) on this request. All other information may be filled in by office staff; **fax to 1-305-671-0200.** No additional phone calls will be necessary if all information (including phone and fax #s) on this form is correct. **If the information provided is not complete, correct, or legible, the authorization process can be delayed.**

Drug Requested: tolvaptan (Jynarque®)

MEMBER & PRESCRIBER INFORMATION: Authorization may be delayed if incomplete.

Member Name: _____

Member AvMed #: _____ **Date of Birth:** _____

Prescriber Name: _____

Prescriber Signature: _____ **Date:** _____

Office Contact Name: _____

Phone Number: _____ **Fax Number:** _____

NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Name/Form/Strength: _____

Dosing Schedule: _____ **Length of Therapy:** _____

Diagnosis: _____ **ICD Code, if applicable:** _____

Weight (if applicable): _____ **Date weight obtained:** _____

TITRATION RECOMMENDATION: per response and tolerability at intervals of at least 7 days

- **Initial:** 60 mg/day in divided doses (45 mg upon waking and 15 mg approximately 8 hours later)
- 90 mg/day (60 mg upon waking and 30 mg approximately 8 hours later), **THEN**
- 120 mg/day (90 mg upon waking and 30 mg approximately 8 hours later)

CLINICAL CRITERIA: Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

Initial Authorization: 12 months

- ☐ Member is $\geq$ 18 years of age
- ☐ Prescribed by or in consultation with a nephrologist and/or specialist experienced in treating Autosomal Dominant Polycystic Kidney Disease (ADPKD)

(Continued on next page)

- ☐ Member has a diagnosis of autosomal dominant polycystic kidney disease confirmed by **ONE** of the following: (please check applicable patient variable. Chart notes **MUST** be submitted detailing progression of disease, family history, and ultrasonographic testing confirming any of the applicable patient variables)
 - ☐ Ultrasonography
 - ☐ Aged 15–29 years: ≥ 3 cysts unilaterally or bilaterally
 - ☐ Aged 30–59: ≥ 2 cysts in each kidney or ≥ 3 cysts unilaterally or bilaterally
 - ☐ Aged ≥ 60 years: ≥ 4 cysts in each kidney
 - ☐ > 10 cysts per kidney if no family history
 - ☐ Magnetic resonance imaging or computed tomography (CT) scan:
 - ☐ ≥ 5 cysts per kidney with family history
 - ☐ ≥ 10 cysts per kidney without family history
- ☐ Member must meet **ONE** of the following:
 - ☐ ADPKD can be categorized as rapidly progressing based on the Mayo Imaging Classification. Please indicate the applicable class below: (results from CT/MRI tests **MUST** be attached)
 - ☐ Class 1C
 - ☐ Class 1D
 - ☐ Class 1E
 - ☐ eGFR decline ≥ 5 mL/min/1.73m² in one year OR eGFR decline ≥ 2.5 mL/min/1.73m² per year over a period of ≥ 5 years
 - ☐ Member has experienced $> 5\%$ total kidney volume (TKV) increase per year (submit results obtained from recent CT/MRI tests)
- ☐ Provide current eGFR at the time of therapy initiation: _____ mL/min/1.73m²
- ☐ Prescriber and patient are enrolled in the Jynarque[®] REMS Program
- ☐ Prescriber will obtain ALT, AST, and bilirubin prior to initiation of therapy, at weeks 2, 4, and then monthly during the first 18 months of therapy (baseline ALT, AST, and bilirubin labs **MUST** be submitted)
- ☐ Member does **NOT** have any of the following:
 - Receiving dialysis
 - Uncorrected abnormal blood sodium level
 - Unable to sense or appropriately respond to thirst
 - Hypovolemia
 - Uncorrected urinary outflow obstruction or anuria
 - Underlying significant liver disease (not including uncomplicated polycystic liver disease)
 - Currently receiving a strong CYP3A inhibitor

(Continued on next page)

Reauthorization: 12 months. Check below all that apply. All criteria must be met for approval. To support each line checked, all documentation, including lab results, diagnostics, and/or chart notes, must be provided or request may be denied.

- ☐ ALT and AST will continue to be monitored as required by the Jynarque® REMS criteria (**current ALT and AST labs must be submitted**)
- ☐ Member has no signs or symptoms consistent with hepatic injury, and recent ALT/AST/bilirubin levels were not more than two times the upper limit of normal
- ☐ Current eGFR at the time of renewal **MUST** be noted: _____ mL/min/1.73m²/year (**submit current lab dated after first year of treatment**)
- ☐ Member does **NOT** have any of the following:
 - Receiving dialysis
 - Uncorrected abnormal blood sodium level
 - Unable to sense or appropriately respond to thirst
 - Hypovolemia
 - Uncorrected urinary outflow obstruction or anuria
 - Underlying significant liver disease (not including uncomplicated polycystic liver disease)
 - Currently receiving a strong CYP3A inhibitor

Medication being provided by Specialty Pharmacy – Proprium Rx

Not all drugs may be covered under every Plan

If a drug is non-formulary on a Plan, documentation of medical necessity will be required.

Use of samples to initiate therapy does not meet step edit/preauthorization criteria.

Previous therapies will be verified through pharmacy paid claims or submitted chart notes.