# SENTARA HEALTH PLANS

## 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 1-800-750-9692**. 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 Sentara #:** _____ **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 wakening and 15 mg approximately 8 hours later)
- 90 mg/day (60 mg upon wakening and 30 mg approximately 8 hours later), **THEN**
- 120 mg/day (90 mg upon wakening 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 ≥ 18 years of age
- ❑ Prescribed by or in consultation with a nephrologist and/or specialist experienced in treating Autosomal Dominant Polycystic Kidney Disease (ADPKD)

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- ❑ 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/1.73m$^2$ in one year OR eGFR decline ≥2.5 mL/min/1.73m$^2$ 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/1.73m$^2$
- ❑ 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

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**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/1.73m$^2$/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.***