OPTIMA HEALTH PLAN

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. **Incomplete form will delay authorization process**.

Drug Requested: Jynarque® (tolvaptan)

DRUG INFORMATION: Complete information below or authorization will be delayed.

Drug Form/Strength: _____

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

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

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: The following criteria **MUST** be met. All relevant chart notes **must** be submitted to support criteria requested**.**

FOR INITIATION OF THERAPY (1 YEAR): ALL responses **must** be checked to qualify to ensure authorization will **NOT** be delayed.

- ❑ Patient is ≥ 18 years of age

  AND

- ❑ Provider is a nephrologist and/or specialist experienced in treating Autosomal Dominant Polycystic Kidney Disease

  AND

- ❑ The patient has a diagnosis of autosomal dominant polycystic kidney disease according to criteria below: Chart notes **MUST** be submitted detailing progression of disease, family history, and ultrasonographic testing confirming any of the applicable patient variables:
  - 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
  - **OR** if family history documentation of ADPKD is not available:
    - Bilateral renal enlargement, AND
    - 10 cysts in each kidney
    - Absence of other manifestations suggesting a different cystic disease

  AND

- ❑ Select the status of patient's kidney function decline and enter values requested. Chart notes and labs **MUST** be submitted documenting the required criteria:

(continued on next page)

- ❑ Age 18-55 years with an estimated GFR between 25 and 65 mL/min/1.73m^2
  - eGFR _____ mL/min/1.73m^2/year

OR

- ❑ Age 56-65 years with an estimated GFR between 25 and 44 mL/min/1.73m^2
  - eGFR _____ mL/min/1.73m^2/year

AND

- ❑ The decline in estimated GFR is greater than 2.0 mL/min/1.73m^2/year
  - calculated decline in GFR year over year _____ mL/min/1.73m^2/year

AND

- ❑ The patient is to be titrated as specified above [**NOTE:** if requesting strengths not in accordance to the titration recommendations, submit chart notes detailing medication history that patient has been titrated accordingly]

AND

- ❑ Prescriber and patient are enrolled in the Jynarque REMS program

AND

- ❑ 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)

AND

- ❑ Chart notes must be submitted to document member's ER visits and pain levels in the last 12 months

FOR CONTINUATION OF THERAPY (1 YEAR): The following criteria **MUST** be met. **ALL** responses must be checked to qualify to ensure authorization will **NOT** be delayed.

- ❑ ALT and AST will continue to be monitored as required by the Jynarque REMS criteria (current ALT and AST labs must be submitted)

AND

- ❑ Patient has no signs or symptoms consistent with hepatic injury

AND

- ❑ Current eGFR must be noted _____ mL/min/1.73m^2/year (current lab must be submitted)

AND

- ❑ Please provide an updated calculated decline from the last 12 months in estimated GFR year over year _____ mL/min/1.73m^2/year

AND

- ❑ Chart notes must be submitted to document decrease in member's ER visits and pain levels from baseline

(Continued on next page; signature page MUST be attached with request)

(Signature page must be included with request.)

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.*

Patient Name: _____

Member Optima #: _____ Date of Birth: _____

Prescriber Name: _____

Prescriber Signature: _____ Date: _____

Office Contact Name: _____

Phone Number: _____ Fax Number: _____

DEA OR NPI #: _____

***Approved by Pharmacy and Therapeutics Committee:** 7/15/2018
UPDATED/REVISED: 11/28/2018