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: Jynarque® (tolvaptan)

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:** _____

DEA OR NPI #: _____

DRUG INFORMATION: Authorization may be delayed if incomplete.

Drug Form/Strength: _____

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

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

Weight: _____ **Date:** _____

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 Approval: 1 year

- ❑ Patient is ≥ 18 years of age

AND

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- ❑ 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 **(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.]

  - ❑ 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

- ❑ Family history documentation of ADPKD is not available and CT/MRI tests confirm the following **(results from tests MUST be attached)**:
  - Bilateral renal enlargement, **AND**
  - 10 cysts in each kidney
  - Absence of other manifestations suggesting a different cystic disease

AND

- ❑ Provide current eGFR at the time of therapy initiation: _____ mL/min/1.73m^2

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 submitted to document member's ER visits and kidney associated pain levels in the last 12 months

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DISEASE PROGRESSION STATUS – SECTION A

- ❑ The patient's condition of ADPKD can be categorized as rapidly progressing based on the Mayo Imaging Classification . Please indicate the applicable class below based on measured disease markers and provide the calculated total kidney volume (TKV) and patient height **(results from CT/MRI tests MUST be attached):**

  Class 1A and Class 1B are **NOT** classified as rapid progressing; reassess status accordingly. See Section B if this request is a reassessment.

  - ❑ Class 1C
  - ❑ Class 1D
  - ❑ Class 1E
  - ❑ TKV _____ **AND** patient height _____ inches (or meters)

DISEASE PROGRESSION STATUS - SECTION B (Optional if patient was previously classified as NOT having rapidly progressing ADPKD)

- ❑ Provide the previously measured height-adjusted TKV: _____ mL

AND

- ❑ The patient has experienced > 5% TKV increase per year **(submit results obtained from recent CT/MRI tests)**

OR

- ❑ The patient is experiencing worsening decline of kidney function observed as ≥ 2.5mL/min/year loss of renal function over a period of 5 years, in the absence of any other cause of acute kidney injury **(submit eGFR measurements covering the span of this time period to confirm status)**

Reauthorization: 1 year. 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)**

AND

- ❑ Patient 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

AND

- ❑ 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)**

AND

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- ❑ Please provide an updated calculated decline from the last 12 months _____ 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

Medication being provided by a Specialty Pharmacy - PropriumRx

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.*

***Approved by Pharmacy and Therapeutics Committee:** 7/15/2018
UPDATED/REVISED/REFORMATTED: ~~11/28/2018; 3/2/2019;10/23/2023;~~ **10/27/2023**