

**Commercial PA Criteria****Effective: July 25, 2018****Prior Authorization:** Tolvaptan oral tablets**Products Affected:** Jynarque (tolvaptan) oral tablet, Tolvaptan oral tablets**Medication Description:**

Jynarque (tolvaptan) is indicated to reduce the decline in kidney function in adults at risk of rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD).

Jynarque is a selective vasopressin V<sub>2</sub>-receptor antagonist, which selectively binds to the V<sub>2</sub>-receptor, causing reduced intracellular levels of adenosine 3', 5'-cyclic monophosphate (cAMP), and leading to increased water excretion without electrolyte loss.

**Covered Uses:** Slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

**Exclusion Criteria:**

1. Patients with a history, signs or symptoms of liver impairment or injury (excluding uncomplicated polycystic liver disease)
2. Patients taking strong CYP3A inhibitors
3. Patients with uncorrected abnormal blood sodium concentrations
4. Patients unable to sense or respond to thirst
5. Patients with hypovolemia
6. Patients with known hypersensitivity (e.g., anaphylaxis, rash) to tolvaptan
7. Patients with uncorrected urinary outflow obstruction
8. Patients with anuria

**Required Medical Information:**

1. Diagnosis
2. Medical history

**Age Restrictions:** 18 years of age or older

**Prescriber Restrictions:** Prescribed by, or in consultation with, a nephrologist or a health care provider specializing in kidney health.

**Coverage Duration:** 1 year

**Other Criteria:****Initial:**

1. Autosomal Dominant Polycystic Kidney Disease. Approve for 1 year if the patient meets ALL of the following (A, B, C, and D):
  - A. Patient is  $\geq 18$  years of age; **AND**
  - B. According to the prescriber, the patient has rapidly-progressing autosomal dominant polycystic kidney disease; **AND**

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*Note: Examples of rapidly declining renal function include estimated glomerular filtration rate decline of  $\geq 3.0$  mL/min/1.73 m<sup>2</sup>, and Mayo Classification of 1D or 1E.*

- C. Patient does not have Stage 5 chronic kidney disease; **AND**

*Note: Stage 5 chronic kidney disease is defined as glomerular filtration rate  $< 15$  mL/min/1.73 m<sup>2</sup> or receiving dialysis.*

- D. The medication is prescribed by or in consultation with a nephrologist.

#### **Continuation**

- A. Approve if the patient meets the following criteria: Patient has baseline ALT, AST and bilirubin

#### **References:**

1. Jynarque® tablets [prescribing information]. Rockville, MD: Otsuka; October 2020.

#### **Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	07/11/2018
2	Update	Updated Per FDA Label	Covered Uses Exclusion Criteria	01/14/2020
3	Update	<p>Addition of Tolvaptan oral tablets to policy.</p> <p>Policy name changed from Jynarque to Tolvaptan</p> <p>Removed Patient has baseline ALT, AST and bilirubin laboratory results within the normal range; AND Patient has a baseline serum sodium concentration <math>&lt;150</math> mEq/L.</p> <p>Addition of Patient does not have Stage 5 kidney disease AND The medication is prescribed by or in consultation with a nephrologist</p> <p>Coverage Duration changed to one year</p>	Prior Authorization Products Affected	6/2/2025