Commercial/Healthcare Exchange PA Criteria

Effective: July 25, 2018

Prior Authorization: Jynarque

Products Affected: Jynarque (tolvaptan) oral tablet

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_2-receptor antagonist, which selectively binds to the V_2-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: Initial: 3 months, Renewal: 6 months

Other Criteria:

Initial:

A. Patient has a diagnosis of autosomal dominant polycystic kidney disease (ADPKD); AND
B. Patient is at risk of rapidly-progressing autosomal dominant polycystic kidney disease (ADPKD); AND
C. Patient has baseline ALT, AST and bilirubin laboratory results within the normal range; AND
D. Patient has a baseline serum sodium concentration <150 mEq/L

Continuation

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

References:

1. Jynarque [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; February 2019.

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