

Clinical Pharmacy Program Guidelines for Jynarque

Program	Prior Authorization
Medication	Jynarque™ (tolvaptan)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	8/2018
Pharmacy and Therapeutics Approval Date	8/2020
Effective Date	10/2020

1. Background:

Jynarque is a selective vasopressin V2-receptor antagonist indicated to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

Jynarque contains a black boxed warning for risk of serious liver injury. See full prescribing information for additional details.

2. Coverage Criteria:

<p>A. <u>Autosomal Dominant Polycystic Kidney Disease</u></p> <p>1. <u>Initial Authorization</u></p> <p>a. Jynarque will be approved based on of the following criterion:</p> <p style="padding-left: 40px;">(1) Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p> <p>2. <u>Reauthorization</u></p> <p>a. Jynarque will be approved based on the following criterion:</p> <p style="padding-left: 40px;">(1) Documentation of positive clinical response to Jynarque therapy</p> <p style="padding-left: 40px;">Authorization will be issued for 12 months.</p>

3. Additional Clinical Rules:

Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.

Supply limits may be in place.

4. References:

1. Jynarque [package insert]. Rockville MD: Otsuka America Pharmaceutical, Inc.; January 2020.

Program	Prior Authorization –Jynarque (tolvaptan)
Change Control	
Date	Change
8/2018	New program
8/2019	Annual review. No changes.
8/2020	Annual review. No changes to coverage criteria. Added Additional Clinical Rules Section. Updated reference.