

UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1251-4
Program	Prior Authorization/Notification
Medication	Jynarque [®] (tolvaptan)
P&T Approval Date	8/2018, 8/2019, 8/2020, 8/2021
Effective Date	11/1/2021; Oxford only: 11/1/2021

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).

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="text-align: center;">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="text-align: center;">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.; October 2020.

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Change Control	
8/2018	New program.
8/2019	Annual review with no changes to coverage criteria.
8/2020	Annual review with no changes to coverage criteria.
8/2021	Annual review with no changes to coverage criteria. Updated reference.