

UnitedHealthcare Pharmacy  
Clinical Pharmacy Programs

Program Number	2024 P 1251-7
Program	Prior Authorization/Notification
Medication	Jynarque® (tolvaptan)
P&T Approval Date	8/2018, 8/2019, 8/2020, 8/2021, 8/2022, 8/2023, 8/2024
Effective Date	11/1/2024

**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<sup>a</sup>:**

<p><b>A. <u>Autosomal Dominant Polycystic Kidney Disease</u></b></p> <p>1. <b><u>Initial Authorization</u></b></p> <p>a. <b>Jynarque</b> will be approved based on of the following criterion:</p> <p>(1) Diagnosis of autosomal dominant polycystic kidney disease (ADPKD)</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p>2. <b><u>Reauthorization</u></b></p> <p>a. <b>Jynarque</b> will be approved based on the following criterion:</p> <p>(1) Documentation of positive clinical response to Jynarque therapy</p> <p style="text-align: center;"><b>Authorization will be issued for 12 months.</b></p> <p><sup>a</sup> State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.</p>
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**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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<b>Change Control</b>	
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.
8/2022	Annual review with no changes to coverage criteria. Added state mandate footnote.
8/2023	Annual review with no changes to coverage criteria.
8/2024	Annual review with no changes to coverage criteria.