



Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	February 27, 2024

Jynarque® (tolvaptan)

LENGTH OF AUTHORIZATION: Up to 6 months

REVIEW CRITERIA:

- Patient must be ≥ 18 years of age; AND
- Patient must have a diagnosis of diagnosis of autosomal dominant polycystic kidney disease (ADPKD); AND
- Baseline alanine aminotransferase (ALT), aspartate aminotransferase (AST), and bilirubin have been performed; AND
- Not have any of the following:
 - History of signs or symptoms of significant liver impairment or injury (not including uncomplicated polycystic liver disease);
 - Uncorrected abnormal blood sodium concentrations;
 - Hypovolemia;
 - Uncorrected urinary outflow obstruction;
 - Anuria

CONTINUATION OF THERAPY

- Patient met initial review criteria.
- Documentation of positive clinical response.
- Most recent ALT, AST, and bilirubin are within normal range (results must be within 3 months of request).
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>
- Available as 15 mg, 30 mg, 45 mg, 60 mg, and 90 mg tablets.