

Clinical Oversight Review Board (CORB) Criteria for Prescribing Tolvaptan (Jynarque)

Notes:

- Quantity Limits: No
- Due to high risk of severe and potentially fatal drug-induced liver injury Jynarque requires enrollment in REMS program
- A boxed warning advises monitoring of ALT, AST, and bilirubin prior to therapy initiation, then 2 and 4 weeks after initiation, then monthly for 18 months, and then every 3 months thereafter.
- Additional considerations before starting Jynarque (tolvaptan):
 - BP controlled (goal <110/75 if 18-50 years old and GFR >60) otherwise <130/85
 - Patient reports they do not use tobacco products
 - ACEI or ARB use if requiring anti-hypertensive and no contraindication
 - 24 urine collection demonstrating dietary sodium restriction not exceeding 2,000 mg per day, AND moderate protein restriction 0.8 grams/kg/day (based on urea appearance).
 - Spot urine osmolality is not more than 280 mOsm/kg on two examinations.
 - Serum phosphorus is less than 4.5 and serum bicarbonate at least 22 meq/L
 - LDL cholesterol less than 100 mg/dL while receiving therapy with a statin.
 - Efforts at exercise and weight management.

Non-Formulary **tolvaptan (Jynarque)** requires a clinical review. Appropriateness of therapy will be based on the following criteria:

Initiation (new start) criteria: Non-formulary **tolvaptan (Jynarque (Brand))** will be covered on the prescription drug benefit when the following criteria are met:

- The prescriber a Nephrologist.
- Patient at least 18 years of age.
- Patient has diagnosis of autosomal dominant polycystic kidney disease (ADPKD) confirmed by either of the following:
 - i. Family history of ADPKD
 - Ultrasonography showing at least 3 cysts per kidney; **OR**
 - Magnetic resonance imaging (MRI) or computed tomography (CT) scan showing at least 5 cysts per kidney.
 - ii. No family history of ADPKD
 - Ultrasonography showing at least 5 cysts per kidney; **OR**
 - MRI or CT scan showing at least 10 cysts per kidney.
- Patient is high risk of disease progression defined by Mayo ADPKD Classification as “Typical (Class 1) ADPKD” and classified as either 1C, 1D, or 1E.
- Patient can be described by one of the following age/renal function groups:

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- i. Age 18 to 50 years; **AND** estimated glomerular filtration rate (eGFR) is at least 60 mL/min/1.73m² **AND** total kidney volume (TKV) is at least 750 mL.
- ii. Age 18 to 55 years; **AND** eGFR is at least 25 to 65 mL/min/1.73m²
- iii. Age 56 to 65 years; **AND** eGFR is at least 25 to 44 mL/min/1.73m²; **AND** eGFR decline is greater than 2 mL/min/1.73m² per year.