Clinical Oversight Review Board (CORB) Criteria for Prescribing / Criteria-Based Consultation (CBC) Criteria for Coverage

CRITERIA FOR PRESCRIBING

Tolvaptan (Jynarque)

Initiation (new start) criteria: Non-formulary tolvaptan (Jynarque) 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:
  - Family history of ADPKD; -AND-
    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.
  - No family history of ADPKD; -AND-
    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:
  - 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.
  - Age 18 to 55 years; AND eGFR is at least 25 to 65 mL/min/1.73m².
  - 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.
Prescriber Notes:

- The first available treatment to slow the decline in kidney function in adults with rapidly progressing ADPKD, to prolonging time to end-stage renal disease (ESRD), dialysis, and transplantation
- Due to high risk of severe and potentially fatal drug-induced liver injury Jynarque requires enrollment in REMS program and access is limited to one Specialty Pharmacy, PantherRx.
- 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.