



Montana Healthcare Programs Drug Prior Authorization Coverage Criteria

Jynarque™ (tolvaptan)

Review Criteria

Member must meet all the following criteria:

INITIAL AUTHORIZATION

- Member must be 18-55 years old
- Diagnosis of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD) required
- Provider and member must both be enrolled in Jynarque Risk Evaluation and Mitigation Strategy (REMS) program, and the following documentation must be provided:
 - Member must not have any of the following:
 - Abnormal blood sodium concentration
 - Hypovolemia
 - Anuria
 - Uncorrected urinary outflow obstruction
 - Existing or history of significant liver impairment or injury unless related to uncomplicated polycystic liver disease
- Provider must agree to obtain baseline alanine transaminase (ALT), aspartate transaminase (AST), bilirubin at baseline, 2 weeks, 4 weeks and monthly during the first 18 months of therapy
- LIMITATIONS:
 - Max daily dosage is 2.0 tablets
 - Initial authorization granted for 6 months

CONTINUATION OF THERAPY

- Prescriber agrees to continue to monitor ALT and AST every 3 months after initial 18-month schedule
- Member must not exhibit any signs or symptoms of hepatic injury
- LIMITATIONS:
 - Maximum daily dosage is 2.0 tablets
 - Continuation authorized for 12-month intervals