

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Rapidly progressing autosomal dominant polycystic kidney disease (ADPKD)

AND ALL of the following:

1. Prescriber and patient are enrolled in the Jynarque REMS program
2. Prescriber agrees to obtain ALT, AST and bilirubin prior to initiation, at weeks 2, 4, and then monthly during the first 18 months of therapy

AND NONE of the following:

1. History of significant liver impairment or injury (does not include uncomplicated polycystic liver disease)
2. Uncorrected abnormal blood sodium concentrations
3. Patient is hypovolemic, anuric, or has an uncorrected urinary outflow obstruction
4. Dual therapy with Samsca (tolvaptan)

Prior - Approval Limits

Quantity 60 tablets per 30 days

Duration 18 months

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnosis

Patient must have the following:

Autosomal dominant polycystic kidney disease (ADPKD)

**JYNARQUE
(tolvaptan)**

AND ALL of the following

1. Prescriber and patient are enrolled in the Jynarque REMS program
2. Prescriber agrees to monitor ALT, AST every 3 months

AND NONE of the following:

1. Signs or symptoms consistent with hepatic injury
2. Uncorrected abnormal blood sodium concentrations
3. Patient is hypovolemic, anuric, or has an uncorrected urinary outflow obstruction
4. Dual therapy with Samsca (tolvaptan)

Prior - Approval *Renewal* Limits

Same as above