

## Pre - PA Allowance

None

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## 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

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## 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