

Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Original Development Date: Original Effective Date: Revision Date:	November 16, 2012 November 23, 2015, July 7, 2017, January 27, 2023

Jynarque™ and Samsca® (tolvaptan)

LENGTH OF AUTHORIZATION: VARIES PER INDICATION

REVIEW CRITERIA:

- Must be ≥ 18 years of age.
- Patient is not taking these medications concurrently.

Jynarque (Approve for up to 1 year)

- **Must have a diagnosis of or is at risk for developing rapidly progressing autosomal dominant polycystic kidney disease** confirmed by an ultrasound, CT, MRI or genetics testing. (*Radiology reports and/or genetics testing results must be provided*).
- Baseline liver function tests (e.g., ALT, AST), and bilirubin must be provided.
- Must be prescribed by, or in consultation with a nephrologist.

Note: Jynarque is available only through a restricted distribution program under a Risk Evaluation and Mitigation Strategy (REMS) called the JYNARQUE REMS Program, because of the risks of liver injury. Further information, including a list of qualified pharmacies/distributors, is available at www.JYNARQUEREMS.com or by telephone at 1-877-726-7220.

Samsca (Approve for date of service or per prescription, up to 30 days)

- **Must have a documented diagnosis of clinically significant hypervolemic or euvolemic hyponatremia** with at least one of the following (*official lab documentation required*):
 - serum sodium level may be below 125 mEq/L **-OR-**
 - serum sodium level ≥ 125 but patient is symptomatic and has resisted correction with fluid restriction.
- Patient does not have underlying liver disease.
- Must be prescribed by, or in consultation with a nephrologist, cardiologist, or related specialist.

DOSING AND ADMINISTRATION:

- Refer to product labeling at <https://www.accessdata.fda.gov/scripts/cder/daf/>