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, August 19, 2024, March 24, 2025

Jynarque® and Samsca® (tolvaptan)

Clinical PA required (preferred): Tolvaptan

Non-Preferred: Jynarque® and Samsca®

LENGTH OF AUTHORIZATION: Varies per indication

REVIEW CRITERIA:

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

Tolvaptan (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.

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 1-866-244-9446.

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 must have documented trial and failure of Tolvaptan (documentation required).

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- Patient does not have underlying liver disease.
- Must be prescribed by, or in consultation with a nephrologist, cardiologist, or related specialist.

CONTINUATION OF THERAPY – Jynarque only

- Patient met initial review criteria.
- Documentation of positive clinical response.
- Most recent ALT, AST, and bilirubin are within normal range (results must be within 3 months of request).
- Dosing is appropriate as per labeling or is supported by compendia.

DOSING AND ADMINISTRATION:

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