



# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Tolvaptan Clinical Edit ( <i>formerly Jynarque® Clinical Edit</i> )
<b>First Implementation Date:</b>	April 11, 2019
<b>Proposed Date:</b>	June 18, 2020
<b>Prepared for:</b>	MO HealthNet
<b>Prepared by:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

## Executive Summary

**Purpose:** Ensure appropriate utilization and control of tolvaptan agents

**Why Issue Selected:** Tolvaptan, a selective vasopressin V<sub>2</sub>-receptor antagonist, is available as 2 different brand name products, each with different indications. Samsca®, FDA approved in 2009, is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia, including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH). Samsca's label contains a box warning stating therapy should be initiated or reinitiated in a hospital setting with monitoring of serum sodium as overly rapid correction to the hyponatremia may occur, possibly causing neurological changes which can result in coma or death. Samsca's box warning also states it is not for use in autosomal dominant polycystic kidney disease (ADPKD). The FDA has determined that Samsca should not be used for longer than 30 days and should not be used in patients with underlying liver disease because it can cause liver injury, potentially requiring liver transplant or death. Jynarque®, FDA approved in 2018, is indicated to slow kidney function decline in adults at risk of rapidly progressing ADPKD. Jynarque comes with a REMS program and a box warning for risk of serious liver injury. Jynarque may be used chronically when in compliance with the REMS program criteria (unlike Samsca). Due to the highly specific indications and adverse event concerns, MO HealthNet will impose criteria to ensure appropriate utilization of tolvaptan agents.

**Program-Specific Information:**

Date Range FFS 4-1-2019 to 3-31-2020				
Drug	Claims	Spend	Cost per tablet (MAC)	Cost per month (MAC)
Jynarque 15 mg tablet	0	-		
Jynarque 30mg tablet	0	-		
Jynarque 45mg-15mg pack	9	\$126,513.78	\$267.22	\$14,964.32
Jynarque 60mg-30mg pack	0	-		
Jynarque 90mg-30mg pack	0	-		
Samsca 15 mg tablet	37	\$323,088.87	\$493.44	\$14,803.20
Samsca 30mg tablet	4	\$14,901.04	\$511.89	\$15,356.70 to \$30,713.40

**Type of Criteria:**  Increased risk of ADE  Preferred Drug List  
 Appropriate Indications  Clinical Edit

Data Sources:  Only Administrative Databases

Databases + Prescriber-Supplied

## Setting & Population

- Drug class for review: Tolvaptan agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older

## Approval Criteria

- Participant aged 18 years or older **AND**
- For Jynarque:
  - Prescribed by or in consultation with a nephrologist or other appropriate specialist in the disease state **AND**
  - Documented diagnosis of rapidly progressing autosomal dominant polycystic kidney disease **AND**
  - Documented eGFR  $\geq$  25 ml/min **AND**
  - Documented baseline and/or current LFTs **AND**
  - Claim does not exceed 2 tablets per day
- For Samsca:
  - Prescribed by or in consultation with a nephrologist, cardiologist, endocrinologist, or other appropriate specialist in the treated disease state **AND**
  - Documented diagnosis of hypervolemic or euvoletic hyponatremia **AND**
  - Claims exceeding 30 days of therapy per year: Clinical Consultant Review required

## Denial Criteria

- Therapy will be denied if no approval criteria are met
- Documented diagnosis of hepatic impairment in the past 2 years

## Required Documentation

Laboratory Results:   
MedWatch Form:

Progress Notes:   
Other:

## Disposition of Edit

Denial: Exception code "0682" (Clinical Edit)  
Rule Type: CE

## Default Approval Period

3 months for Jynarque  
**1 month for Samsca**

## References

- SAMSCA® (tolvaptan) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; June 2018.
- JYNARQUE® (tolvaptan) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; January 2020.
- IPD Analytics. Syndrome of Inappropriate Antidiuretic Hormone (SIADH). May 2020.

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- IPD Analytics. New Drug Approval: Jynarque (tolvaptan). August 2018.
- Clinical Pharmacology. Tolvaptan. Accessed May 28, 2020.
- Facts & Comparisons. Tolvaptan Oral. Accessed May 28, 2020.
- U.S. Food & Drug Administration. FDA Drug Safety Communication: FDA limits duration and usage of Samsca (tolvaptan) due to possible liver injury leading to organ transplant or death. May 12, 2017.  
<https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-limits-duration-and-usage-samsca-tolvaptan-due-possible-liver>

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