MEDICAL MUTUAL®

Drug Policy

Policy:	Samsca and Jynarque (tolvaptan)	Annual Review Date: 05/18/2023 Last Revised Date: 05/18/2023

OVERVIEW

Samsca, a selective vasopressin V_2-receptor antagonist, is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure (HF) and syndrome of inappropriate antidiuretic hormone (SIADH). Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with Samsca. Samsca has a Boxed Warning that patients should be in a hospital for initiation and re-initiation of therapy to assess the therapeutic response. Too rapid of a correction of hyponatremia can lead to osmotic demyelination causing dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma, and death. Jynarque indication is to slow kidney function decline in adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD).

POLICY STATEMENT

This policy involves the use of Samsca, Jynarque, and generic tolvaptan. Prior authorization is recommended for pharmacy benefit coverage of Samsca, Jynarque, and generic tolvaptan. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Jynarque as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Jynarque be prescribed by or in consultation with a physician who specializes in the condition being treated. All approvals for initial therapy are provided for the initial approval duration noted below; if reauthorization is allowed, a response to therapy is required for continuation of therapy unless otherwise noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of **Samsca or generic tolvaptan** is recommended in those who meet the following criteria:

1. **Hyponatremia**
   Criteria. *Approve Samsca or generic tolvaptan if the patient meets all of the following criteria:*

   i. The patient meets one of the following:
      i. The patient has a serum sodium < 125 mEq/L at baseline; OR

ii. The patient has less marked hyponatremia, defined as serum sodium < 135 mEq/L at baseline, that is symptomatic (e.g., nausea, vomiting, headache, lethargy, confusion) and has resisted correction with fluid restriction; OR
iii. The patient has already been started on Samsca and has received < 30 days of therapy; AND

ii. If brand Samsca is requested, the patient has failed a trial of generic tolvaptan AND the brand is being requested due to formulation differences in inactive ingredients

Coverage of **Jynarque** is recommended in those who meet the following criteria:

1. **<u>At Risk Patients for Rapidly Progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD)- initial</u>**
Criteria. *Approve Jynarque if the patient meets all of the following criteria:*

i. Medication requested is being used to slow kidney function decline; AND
ii. Patient is 18 years of age or older; AND
iii. Liver function laboratory values (ALT, AST and bilirubin) have been reviewed and are appropriate before initiation; AND
iv. The requested drug is prescribed by or under consultation with a nephrologist

2. **<u>At Risk Patients for Rapidly Progressing Autosomal Dominant Polycystic Kidney Disease (ADPKD)- continuation</u>**
Criteria. *Approve Jynarque if the patient meets all of the following criteria:*

i. Medication requested is being used to slow kidney function decline; AND
ii. The requested drug is prescribed by or under consultation with s a nephrologist; AND
iii. Patient's kidney function (total kidney volume (TKV), albuminuria, onset or progression of hypertension, eGFR, etc.) decline has slowed and/or kidney pain has improved per provider since treatment with Jynarque; AND
iv. Provider is monitoring liver function monthly for the first 18 months of treatment, then every 3 months

Initial Approval/ Extended Approval.
A) *Initial Approval:* hyponatremia- 30 days
ADPKD - 90 days
B) *Extended Approval:* *hyponatremia- not recommended*
ADPKD - 1 year (365 days)

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Solaraze has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. **Concomitant use of Samsca/generic tolvaptan and Jynarque.** Samsca and Jynarque are both tolvaptan products with different indications. Samsca is indicated for the treatment of clinically-significant hypervolemic and euvolemic

hyponatremia, while Jynarque is indicated to slow kidney function decline in adults at risk of rapidly-progressing ADPKD. Concomitant use is not recommended.

2. **Patients Requiring Intervention to Raise Serum Sodium Urgently to Prevent or to Treat Serious Neurological Symptoms.** Tolvaptan products have not been studied in a setting of urgent need to raise serum sodium acutely.

3. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Jynarque [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical,Inc; October 2020.
2. Samsca® tablets for oral use [prescribing information]. Rockville, MD: Otsuka Pharmaceuticals; April 2021.
3. Torres VE, Chapman AB, Devuyst O, et al, for the TEMPO 3:4 trial investigators. Tolvaptan in patients with autosomal dominant polycystic kidney disease. N Engl J Med. 2012;367(25):2407-2418.
4. Schrier RW, Gross P, Gheorghiade M, et al, for the SALT Investigators. Tolvaptan, a selective oral vasopressin V2-receptor antagonist, for hyponatremia. N Engl J Med. 2006;355:2099-2112.
5. Tolvaptan. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 3 May 2023. Accessed on 18 May 2023.