ALASKA MEDICAID
Prior Authorization Criteria

Jynarque™, Samsca®
(tolvaptan)

FDA INDICATIONS AND USAGE[1,3]

Tolvaptan is a selective vasopressin V2-receptor antagonist. Jynarque™ is indicated to slow kidney function decline on adults at risk of rapidly progressing autosomal dominant polycystic kidney disease (ADPKD). Samsca® 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 and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).

APPROVAL CRITERIA[1,2,3]

Jynarque™ request:

1. Patient is 18 years of age or older **AND**;
2. Patient has a diagnosis of autosomal dominant polycystic kidney disease and is at risk for kidney function decline **AND**;
3. Is being prescribed by or in consultation with a nephrologist **AND**;
4. Any abnormal sodium concentrations have been corrected **AND**;
5. The patient has had a liver function test, showing results deemed appropriate prior to treatment **AND**;
6. Prescriber agrees to check liver function at week 2 and 4, then monthly during the first 18 months of therapy.

Samsca® request:

1. Patient has the diagnosis of clinically significant hypervolemic or euvolemic hyponatremia defined by:
    a. Serum sodium is less than 125 mEq/L **OR**;
    b. Serum sodium is 125 mEq/L or greater AND patient has symptomatic hyponatremia that has resisted correction with fluid restriction
2. The requested medication will be or has been initiated in the hospital where serum sodium can be closely monitored **AND**;
3. Is being prescribed by or in consultation with a nephrologist, cardiologist, or endocrinologist **AND**;
4. Prescriber agrees to monitor liver function while the patient is taking medication **AND**;
5. Duration of therapy requested is 30 days or less.

DENIAL CRITERIA[1,2,3]

1. Failure to meet approval criteria **OR**;
2. Patient has history of significant liver impairment or injury **OR**;
3. Patient is unable to sense or appropriately respond to thirst **OR**;
4. Patient is hypovolemic, anuric, or has an uncorrected urinary outflow obstruction **OR**;
5. Patient is concomitantly using a strong CYP 3A inhibitor.

CAUTIONS[1,3]

- Serious liver injury has occurred, avoid use in patients with underlying liver disease.
- Monitor for hypernatremia, dehydration, and hypovolemia.
- Dose reductions may be recommended for patients taking a moderate CYP 3A inducer.

DURATION OF APPROVAL

- Initial Approval: up to 90 days
- Reauthorization Approval: up to 12 months

QUANTITY LIMIT

- Jynarque™
  - 45mg and 15mg kit - 56 tablets per 28 days
  - 60mg and 30mg kit - 56 tablets per 28 days
  - 90mg and 30mg kit - 56 tablets per 28 days
  - 15mg tablets – 30 per 30 days
  - 30mg tablets – 30 per 30 days
- Samsca®
  - 15mg tablets – 30 tablets per 30 days
  - 30mg tablets – 60 tablets per 30 days

REFERENCES / FOOTNOTES:

1. Jynarque™ [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical Inc.; February 2019.
2. Torres VE, Chapman AB, Devuyst O, et al. for the Tempo 3:4 trial investigators. Tolvaptan in patients with autosomal dominant polycystic kidney disease. New England Journal of Medicine, 2012;367(25):2407-2418.
3. Samsca® [prescribing information]. Rockville, MD: Otsuka America Pharmaceutical Inc; April 2021.