JOHNS HOPKINS HEALTH PLANS	Johns Hopkins Health Plans **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS064
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	Subject **Tolvaptan (Samsca and Jynarque)**	*Revision Date*	10/18/2023
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Jynarque, Samsca

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I. POLICY

A. Tolvaptan (Samsca®, Jynarque®) will require prior authorization to ensure appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Tolvaptan** (generic Samsca) may be approved for patients meeting the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing one of the following:
      a. Patient has clinically significant hypervolemic or euvolemic hyponatremia (serum sodium < 125 mEq/L)
      b. Patient has less marked hyponatremia (serum sodium < 135mEq/L), but is symptomatic and is resistant to correction with fluid restriction

B. **Brand Samsca** may be approved for patients meeting the following:
   1. Patient has met the criteria for coverage of generic tolvaptan (noted above)
   2. Documentation has been submitted showing trial and inadequate response to generic tolvaptan

C. **Jynarque** may be approved for patients, who meet the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing a diagnosis of autosomal dominant polycystic kidney disease (ADPKD) and Jynarque is being requested to slow kidney function decline
   3. Liver function laboratory values (ALT, AST and bilirubin) have been assessed prior to therapy initiation
   4. Jynarque is prescribed by or under consultation with an endocrinologist, nephrologist, or transplant specialist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Tolvaptan (Samsca) may be approved for 30 days of therapy at doses less than or equal to the maximum recommended dose of 60 mg/day.

B. Initial approval for Jynarque will be limited to 3 months of therapy at doses less than or equal to the maximum recommended dose of 120 mg/day

1. Continuation of therapy with Jynarque may be approved in 12-month intervals with documentation showing the patient's kidney function decline has slowed, and the prescriber is monitoring liver function values monthly for the first 18 months of therapy, and then every 3 months.

IV. EXCLUSIONS

A. **Tolvaptan (Samsca)** will not be approved for the following:

1. Patients that require urgent intervention to raise serum sodium acutely
2. Patients who are unable to sense or to respond appropriately to thirst
3. Patients with hypovolemic hyponatremia
4. Patients taking concomitant strong CYP 3A inhibitors (i.e. clarithromycin, ketoconazole, itraconazole ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, and telithromycin)
5. Patients who are anuric
6. Treatment of autosomal dominant polycystic kidney disease (ADPKD) outside of FDA-approved REMS
7. Any indications or uses that are not FDA-approved, or guideline-supported

B. **Jynarque** will not be approved for the following:

1. Patients with uncorrected abnormal blood sodium concentrations
2. Patients with uncorrected urinary outflow obstruction
3. Patients who are unable to sense or to respond appropriately to thirst
4. Patients with hypovolemia
5. Patients taking concomitant strong CYP 3A inhibitors (i.e. clarithromycin, ketoconazole, itraconazole ritonavir, indinavir, nelfinavir, saquinavir, nefazodone, and telithromycin)
6. Patients who are anuric
7. Patients with a history, signs, or symptoms of significant liver impairment or injury
8. Any indications or uses that are not FDA-approved, or guideline-supported

C. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Samsca [prescribing information]. Otsuka America Pharmaceutical, Inc; Rockville, MD; April 2021.
2. Jynarque [prescribing information]. Otsuka America Pharmaceutical, Inc; Rockville, MD; October 2020.
3. Lewis, J.L. Hyponatremia: fluid and electrolyte metabolism. In: Merck Manual Professional, Merck & Co., Inc., Whitehouse Station, N.J., 2009.
4. Rose, B.D. Treatment of hyponatremia. In: UpToDate, Sterns, R.H. (Ed), UpToDate, Waltham, MA, 2009.
5. Ho, J.E., Teerlink, J.R. Role of tolvaptan in acute decompensated heart failure. Expert Review of Cardiovascular Therapy, Jun 2008, Vol. 6, No. 5, Pages 601-608.

VI. APPROVALS

Signature on file at JHHC

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DATE OF REVISION	SUMMARY OF CHANGE
03/30/2016	Removed background information
07/27/2017	Updated Exclusions section regarding physician samples
07/18/2018	Added clinical criteria for Jynarque
01/19/2022	Updated clinical criteria and added exclusions for Jynarque
10/18/2023	Clarified clinical criteria

Review/Revision Dates: 11/12/2009, 3/30/2016, 07/27/2017, 07/18/2018, 01/19/2022, 10/18/2023