Clinical Policy Title:	tolvaptan
Policy Number:	RxA.277
Drug(s) Applied:	Jynarque®, Samsca®
Original Policy Date:	02/07/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. **Initial Approval Criteria**

A. **Autosomal Dominant Polycystic Kidney Disease** (must meet all)**:**

1. Diagnosis of ADPKD;
2. Request is for Jynarque®;
3. Prescribed by or in consultation with a nephrologist;
4. Age ≥ 18 years;
5. Dose does not exceed 120 mg/day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

B. **Hyponatremia** (must meet all)**:**

1. Diagnosis of hypervolemic or euvolemic hyponatremia;
2. Request is for Samsca®;
3. Prescribed by or in consultation with a nephrologist, cardiologist, or endocrinologist;
4. Recent (within the last 7 days) serum sodium level < 125 mEq/L, unless hyponatremia is symptomatic and has resisted correction with fluid restriction;
5. Age ≥ 18 years;
6. Dose does not exceed 60 mg per day.

Approval duration
Commercial: 30 days
Medicaid: 30 days

II. **Continued Therapy Approval**

A. **Autosomal Dominant Polycystic Kidney Disease** (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 120 mg/day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

B. **Hyponatremia** (must meet all)**:**
   1. Member is currently receiving medication that has been authorized by RxAdvance or the member has met initial approval criteria listed in this policy;
   2. Member is responding positively to therapy as evidenced by increased sodium level since baseline;
   3. If request is for a dose increase, new dose does not exceed 60 mg/day.

   Approval duration
   Commercial: 30 days
   Medicaid: 30 days

References

1. Muller RU, Haas CS, Sayer JA. Practical approaches to the management of autosomal dominant polycystic kidney disease patients in the era of tolvaptan. Clin Kidney J, 2018 Feb; 11(1):62-69. Available at: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5798152/. Accessed January 02, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	02/07/2020
Policy was reviewed: 1. Clinical Policy Title was updated. 2. Line of Business Policy Applies to was updated. 3. Initial and Continued approval duration was updated to include Medicaid, Commercial & HIM approval duration. 4. Continued therapy criteria II.A.1. & II.B.1. was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 5. References were reviewed and updated.	07/17/2020	09/14/2020
Policy was reviewed: 1. HIM approval duration was removed from Initial and continued approval criteria. 2. References were reviewed and updated.	04/02/2021	06/10/2021
Policy was reviewed: 1. References were reviewed and updated.	01/07/2022	04/18/2022
Policy was reviewed: 1. References were reviewed and updated.	01/02/2023	04/13/2023
Policy was reviewed.	10/19/2023	10/19/2023