Clinical Policy Title:	tolvaptan
Policy Number:	RxA.277
Drug(s) Applied:	tolvaptan, tolvaptan (hyponatremia)
Original Policy Date:	02/07/2020
Last Review Date:	5/14/2026
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. **Initial Approval Criteria**

A. Autosomal Dominant Polycystic Kidney Disease (tolvaptan oral tablets):

1. Diagnosis of autosomal dominant polycystic kidney disease.

Approval duration

All Lines of Business (except Medicare): 12 months

B. Hyponatremia, Hypervolemic or euvolemic (tolvaptan hyponatremia oral tablets)

1. Diagnosis of hypervolemic or euvolemic hyponatremia.

Approval duration

All Lines of Business (except Medicare): 12 months

II. **Continued Therapy Approval**

A. All indications (must meet all)**:**

1. Member is currently receiving medication in the past 120 days that has been authorized by RxAdvance or the member has met the initial approval criteria.

Approval duration

All Lines of Business (except Medicare): 12 months

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 March 21, 2025.
2. Tolvaptan. Clinical Pharmacology. Elsevier Inc, 2024.https://www.clinicalkey.com/pharmacology/monograph/3541?n=Samsca. Accessed March 21, 2025.

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	07/17/2020	09/14/2020

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

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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.		
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
Policy was reviewed: 1. Updated continued therapy approval for both indications 2. Samsca: Added “Treatment has been initiated in a hospital setting within the past 30 days” 3. Samsca: Removed reauth criteria. Member must meet initial criteria	4/1/2024	4/1/2024
Policy was reviewed: 1. Removed prescriber restrictions. 2. Added “Split-fill” to initial criteria approval duration. 2. Updated Continued therapy approval to “Member is currently receiving medication that has been authorized..”	11/28/2024	12/05/2024
Policy was reviewed: 1. Updated continuation of therapy language. 2. References were reviewed and updated.	03/21/2025	04/10/2025
Policy was reviewed: 1. Jynaryque removed from policy	12/11/2025	12/11/2025
Policy was reviewed 1. Diagnosis of hypervolemic or euvolemic hyponatremia added.	5/14/2026	N/A

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