

Pharmacy Drug Policy & Procedure

Policy Name:	Samsca (tolvaptan)	Policy #:	2451P
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Purpose of the Policy

The purpose of this policy is to establish the criteria for coverage of Samsca and tolvaptan

Statement of the Policy

Health Alliance Medical Plans will approve the use of Samsca and tolvaptan under the specialty pharmacy benefit when the following criteria have been met.

Criteria

1. Coverage Criteria for Treatment of Hypervolemic or Euvolemic Hyponatremia

- 1.1 Diagnosis of clinically significant high volume or normal volume low sodium levels indicated by low blood sodium (<125 mEq/L) or less severe low blood sodium with symptoms that cannot be corrected by fluid restriction
- 1.2 Treatment started in the hospital
- 1.3 Dosing will be limited so that the maximum increase in blood sodium levels is 12 mEq/L within 24 hours
- 1.4 Documentation that the member is not experiencing urine blockage
- 1.5 All strong CYP3A inhibitors will be discontinued
- 1.6 Not for use in patients with autosomal dominant polycystic kidney disease (ADPKD)
- 1.7 For brand Samsca, documented trial and failure of generic tolvaptan tablets.

2. Approval Period

- 2.1 One 30-day supply within 6 months
 - Use beyond 30 days is not recommended due to risk of liver function decline

CPT Codes

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HCPCS Codes

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References

1. Samsca (tolvaptan) [prescribing information]. Rockville, MD: Otsuka Pharmaceutical Inc; April 2021.

2. Verbalis JG, Goldsmith SR, Greenberg A, et al. Diagnosis, evaluation, and treatment of hyponatremia: expert panel recommendations. *Am J Med.* 2013 Oct;126(10 Suppl 1):S1-42.
3. Schrier RW, Gross P, Gheorghiade M, et al. Tolvaptan, a selective oral vasopressin V2-receptor antagonist, for hyponatremia. *N Engl J Med.* 2006; 355(20):2099–2112.
4. Cárdenas A, Ginès P, Marotta P, et al. Tolvaptan, an oral vasopressin antagonist, in the treatment of hyponatremia in cirrhosis. *J Hepatol.* 2012;56(3):571-578.

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DISCLAIMER

This Medical Policy has been developed as a guide for determining medical necessity. The process of medical necessity review also entails review of the most recent literature and physician review. Medical Policy is not intended to dictate to providers how to practice medicine. Providers are expected to exercise their medical judgment in providing the most appropriate care. Health Alliance encourages input from providers when developing and implementing medical policies. Benefit determinations are based on applicable contract language in the member's Policy/ Subscription Certificate/ Summary Plan Description. This Medical Policy does not guarantee coverage. There may be a delay between the revision of this policy and the posting on the web. Please contact the Health Alliance Customer Service Department at 1-800-851- 3379 for verification of coverage.