Samsca (tolvaptan)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	30 days* *Therapy duration is limited to 30 days to limit hepatic injury risk associated with medication use.

Medications	Quantity Limit
Samsca (tolvaptan) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Samsca (tolvaptan) may be approved if the following criteria are met:

I. Individual is 18 years of age or older; **AND**
II. Individual has a diagnosis of clinically significant hypervolemic or euvolemic hyponatremia; **AND**
III. Individual is being initiated or re-initiated on therapy in a hospital setting; **AND**
IV. Individual has a serum sodium of less than 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction.

Samsca (tolvaptan) may not be approved for the following:

I. Individual requires an acute, urgent need to raise serum sodium; **OR**
II. Individual is unable to sense or appropriately respond to thirst; **OR**
III. Individual has a diagnosis of hypovolemic hyponatremia; **OR**
IV. Individual is using to treat autosomal dominant polycystic kidney disease; **OR**
V. Individual has an uncorrected urinary outflow obstruction; **OR**
VI. Individual is anuric; **OR**
VII. Individual has underlying liver disease, including cirrhosis; **OR**
VIII. Individual is currently receiving a strong CYP 3A inhibitor (such as, clarithromycin, ketoconazole, itraconazole, ritonavir, indinavir, nelfinavir, saquinavir, nefazodone) (FDA).

Notes:
Samsca (tolvaptan) has black box warnings for the need to initiate and re-initiate in a hospital and monitoring of serum sodium. Therapy should be initiated or re-initiated only in a hospital setting where serum sodium can be monitored to prevent too-rapid in correction of hyponatremia (greater than 12 mEq/L/24 hours). Too rapid correction of hyponatremia can cause osmotic demyelination resulting in dysarthria, mutism, dysphagia, lethargy, affective changes, spastic quadriparesis, seizures, coma and death. Slower rates of sodium correction may be advisable in susceptible individuals, including those with severe malnutrition or alcoholism. Samsca should not be used in individuals with an urgent need to raise serum sodium.

Samsca also has a black box warning advising it should not be used to treat autosomal dominant polycystic kidney disease (ADPKD). Tolvaptan has been associated with serious and potential fatal liver injury. Use of tolvaptan to treat ADPKD should be in accordance with the FDA-approved REMS program for Jynarque.

Key References:

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: July 11, 2021.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
4. US Food and Drug Administration. Drug Development and Drug Interactions: Table of Substrates, Inhibitors and Inducers. Last updated: March 10, 2020. Available at https://www.fda.gov/drugs/developmentapprovalprocess/developmentresources/druginteractionslabeling/ucm093664.htm. Accessed: July 11, 2021.