Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: ***Samsca (tolvaptan)***
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***July 2009 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Samsca (tolvaptan).

Samsca (tolvaptan) is indicated for for the treatment of clinically significant hypervolemic and euvolemic hyponatremia (serum sodium < 125 mEq/L or less marked hyponatremia that is symptomatic and has resisted correction with fluid restriction), including patients with heart failure, and Syndrome of Inappropriate Antidiuretic Hormone (SIADH).

- Important Limitations: Patients requiring intervention to raise serum sodium urgently to prevent or to treat serious neurological symptoms should not be treated with tolvaptan. It has not been established that raising serum sodium with tolvaptan provides a symptomatic benefit to patients.

DEFINITIONS

Hyponatremia – an excess of water in relation to the sodium in extracellular fluid

Symptoms of hyponatremia – mild: headache, difficulty concentrating, impaired memory, muscle cramps, weakness, and dysgeusia; severe: confusion, hallucinations, seizures, coma, decerebrate posture, and respiratory arrest.

Syndrome of Inappropriate Antidiuretic Hormone (SIADH) – a disorder of sodium and water balance characterized by urinary dilution impairment and hypotonic hyponatermia, in the absence of renal disease or any identifiable non-osmotic stimulus able to induce antidiuretic hormone release.

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.002 Pharmacy and Therapeutics Committee and RX.003-Prior Authorization Process.

The drug, Samsca (tolvaptan), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- Must be prescribed by an endocrinologist or a nephrologist.
- Must have a diagnosis of hypervolemic or euvolemic hyponatremia and one of the following prior to beginning tolvaptan:
    - Serum sodium < 125 mEq/L OR
    - Symptomatic hyponatremia that resisted correction with 72 hours of both interventions:
        - Consideration of discontinuation of agents known to cause SIADH when clinically feasible (e.g. chlorpropamide, selective serotonine reuptake inhibitors (SSRIs), tricyclic antidepressants, clofibrate, carbamazepine, vincristine, nicotine, narcotics, antipsychotic drugs, ifosfamide, cyclophosmamide, NSAIDS, MDMA, desmopressin, oxytocin, vasopressin)
        - Fluid restriction (< 1000 mL/day)
- For members where SIADH is the underlying cuase of hyponatremia, member must have a confirmed diagnosis of SIADH by an endocrinologist. Chart documentation of a clinical work-up to rule out other diagnoses and clinical rationale for the diagnosis and exclusion of other diagnoses must be rovided. Must demonstrate all of the following:

  - Decreased plasma osmolality (<275 mosm/kg)
  - Increased urinary osmolality (>100 mosm/kg)
  - Urinary sodium >20 mmol/L with normal dietary salt intake
  - Clinical euvolemia
  - Normal thyroid and adrenal function
  - No recent use of antidiuretics within 24 hours or laboratory testing
- Must be initiated and titrated in a hospital setting with close serum sodium monitoring
- Must have CrCl >10 mL/min
- Must not be anuric
- Must be able to sense and respond appropriately to thirst
- Must not be on concomitant therapy with a strong CYP3A inhibitor
- Must not have hypovolemic hyponatremia
- Must not have underlying liver disease, including cirrhosis

Reauthorization Criteria:
Due to risk of liver injury, Samsca (tolvaptan) should not be administered for more than 30 days.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	• Up to 1 month
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Samsca (tolvaptan) [package insert]. Rockville, MD: Otsuka America Pharmaceuticals; April 2013.
2. Verbalis JG, Goldsmith SR, Greenberg A, et al. Hyponatremia treatment guidelines 2007: expert panel recommendations. *Am J Med* 2007;120(11 Suppl 1):S1-S21.
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. Torres VE, Chapman AB, Devuyst O, et al. Tolvaptan in patients with autosomal dominant polycystic kidney disease. *N Eng J Med* 2012;367:2407-2418

RECORD RETENTION
Records Retention for Evolent Health documents, regardless of medium, are provided

within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual review	*02/17, 02/18*