SmartPA Criteria Proposal

Drug/Drug Class:	Tolvaptan Clinical Edit
First Implementation Date:	April 11, 2019
Proposed Date:	June 17, 2021
Prepared for:	MO HealthNet
Prepared by:	MO HealthNet/Conduent
Criteria Status:	☒Existing Criteria ☐Revision of Existing Criteria ☐New Criteria

Executive Summary

Purpose: Ensure appropriate utilization and control of tolvaptan agents

Why Issue Selected: Tolvaptan, a selective vasopressin V_2-receptor antagonist, is available as 2 different brand name products, each with different indications. Samsca®, FDA approved in 2009, is indicated for the treatment of clinically significant hypervolemic and euvolemic hyponatremia, including patients with heart failure and Syndrome of Inappropriate Antidiuretic Hormone (SIADH). Samsca's label contains a box warning stating therapy should be initiated or reinitiated in a hospital setting with monitoring of serum sodium as overly rapid correction to the hyponatremia may occur, possibly causing neurological changes which can result in coma or death. Samsca's box warning also states it is not for use in autosomal dominant polycystic kidney disease (ADPKD). The FDA has determined that Samsca should not be used for longer than 30 days and should not be used in patients with underlying liver disease because it can cause liver injury, potentially requiring liver transplant or death. Jynarque®, FDA approved in 2018, is indicated to slow kidney function decline in adults at risk of rapidly progressing ADPKD. Jynarque comes with a REMS program and a box warning for risk of serious liver injury. Jynarque may be used chronically when in compliance with the REMS program criteria (unlike Samsca). Due to the highly specific indications and adverse event concerns, MO HealthNet will impose criteria to ensure appropriate utilization of tolvaptan agents.

Program-Specific Information:

Date Range FFS 4-1-2020 to 3-31-2021			
Drug	**Claims**	**Spend**	**Avg Spend per Claim**
JYNARQUE 15 MG TABLET	1	$14,974.27	$14,974.27
JYNARQUE 30 MG TABLET	0	-	-
JYNARQUE 15 MG-15 MG PACK	6	$89,845.62	$14,974.27
JYNARQUE 30 MG-15 MG PACK	2	$30,995.37	$15,497.68
JYNARQUE 45 MG-15 MG PACK	11	$164,716.97	$14,974.27
JYNARQUE 60 MG–30 MG PACK	1	$14,973.57	$14,973.57
JYNARQUE 90 MG–30 MG PACK	0	-	-
SAMSCA 15 MG TABLET	36	$282,946.02	$7,859.61
SAMSCA 30 MG TABLET	2	$10,266.54	$5,133.27

Type of Criteria:

☐ **Increased risk of ADE**
☒ **Appropriate Indications**
☐ **Preferred Drug List**
☒ **Clinical Edit**

Data Sources: ☐ **Only Administrative Databases** ☒ **Databases + Prescriber-Supplied**

Setting & Population

- Drug class for review: Tolvaptan agents
- Age range: All appropriate MO HealthNet participants aged 18 years or older

Approval Criteria

- Participant aged 18 years or older **AND**
- For Jynarque:
  - Prescribed by or in consultation with a nephrologist or other appropriate specialist in the disease state **AND**
  - Documented diagnosis of rapidly progressing autosomal dominant polycystic kidney disease **AND**
  - Documented eGFR ≥ 25 ml/min **AND**
  - Documented baseline and/or current LFTs **AND**
  - Claim does not exceed 2 tablets per day
- For Samsca:
  - Prescribed by or in consultation with a nephrologist, cardiologist, endocrinologist, or other appropriate specialist in the treated disease state **AND**
  - Documented diagnosis of hypervolemic or euvolemic hyponatremia **AND**
  - Claims exceeding 30 days of therapy per year: Clinical Consultant Review required

Denial Criteria

- Therapy will be denied if all approval criteria are not met
- Documented diagnosis of hepatic impairment

Required Documentation

Laboratory Results:	X	Progress Notes:	
MedWatch Form:		Other:	X

Disposition of Edit

Denial: Exception code “0682” (Clinical Edit)
Rule Type: CE

Default Approval Period

3 months for Jynarque
1 month for Samsca

References

- SAMSCA® (tolvaptan) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; April 2021.

- JYNARQUE® (tolvaptan) [package insert]. Rockville, MD: Otsuka America Pharmaceutical, Inc.; October 2020.
- IPD Analytics. Renal: CKD - Phosphate Binders, Hyponatremia. Accessed May 14, 2021.
- IPD Analytics. Renal: Chronic Kidney Disease. Accessed May 14, 2021.
- IPD Analytics. Syndrome of Inappropriate Antidiuretic Hormone (SIADH). May 2020.
- IPD Analytics. New Drug Approval: Jynarque (tolvaptan). August 2018.
- U.S. Food & Drug Administration. FDA Drug Safety Communication: FDA limits duration and usage of Samsca (tolvaptan) due to possible liver injury leading to organ transplant or death. May 12, 2017. https://www.fda.gov/drugs/drug-safety-and-availability/fda-drug-safety-communication-fda-limits-duration-and-usage-samsca-tolvaptan-due-possible-liver