Drug/Drug Class: Tolvaptan Clinical Edit
First Implementation Date: April 11, 2019
Revised Date: October 28, 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 V2-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:

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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
MedWatch Form: 
Progress Notes: 
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