

SmartPA Criteria Proposal

Drug/Drug Class:	Bile Salt Agents PDL Edit
First Implementation Date:	June 23, 2011
Proposed Date:	June 18, 2020
Prepared For:	MO HealthNet
Prepared By:	MO HealthNet/Conduent
Criteria Status:	<input type="checkbox"/> Existing Criteria <input checked="" type="checkbox"/> Revision of Existing Criteria <input type="checkbox"/> New Criteria

Executive Summary

Purpose: The MO HealthNet Pharmacy Program will implement a state-specific preferred drug list.

Why Issue Selected: Gallstones are crystallized pieces of bile found in the gall bladder. In general, either cholesterol or bilirubin precipitates out of solution to form stones, but not both. In the United States, almost 80% of participants with gallstones have cholesterol stones. Gallstone diseases affect 10 to 15 percent of the U.S. population, with close to 1 million new cases diagnosed each year. Participants with gallstone diseases may be asymptomatic or present with biliary colic or complications of gallstone disease. Gallstone blockages of the cystic duct result in pain and inflammation, which may lead to fever, jaundice, and infections. Treatment is usually unnecessary if gallstones are not causing symptoms. If treatment is warranted, cholecystectomy is the most widely used therapy. Alternatively, dissolution of the stones by chemicals – ursodiol or chenodiol is used rather than surgery. These oral agents thin the bile and allow stones to dissolve. In addition, ursodiol decreases cholesterol in bile and bile stones by reducing the secretion of cholesterol from the liver and the fractional reabsorption of cholesterol by the intestines. Use of drugs is limited to small stones which are predominantly composed of cholesterol, allowing for rapid and complete dissolution. The most common adverse effects include headache, diarrhea, constipation, dizziness, nausea, and dyspepsia.

Total program savings for the PDL classes will be regularly reviewed.

Program-Specific Information:	Preferred Agents	Non-Preferred Agents
	<ul style="list-style-type: none"> Ursodiol Caps/Tabs 	<ul style="list-style-type: none"> Actigall® Chenodal® Cholbam® Ocaliva® Urso Forte® Urso®

Type of Criteria: Increased risk of ADE Preferred Drug List
 Appropriate Indications Clinical Edit

Data Sources: Only Administrative Databases Databases + Prescriber-Supplied

Setting & Population

- Drug class for review: Bile Salt Agents
- Age range: All appropriate MO HealthNet participants

Approval Criteria

- Documented compliance on current therapy regimen **OR**
- Failure to achieve desired therapeutic outcomes with trial on 1 or more preferred agents
 - Documented trial period of preferred agents **OR**
 - Documented ADE/ADR to preferred agents **OR**
- For Cholbam: approved as first-line therapy with a documented diagnosis of sterol nucleus synthesis or side-chain synthesis disorder **OR** peroxisomal disorders with history of compliance with adjunct therapy

Denial Criteria

- Lack of adequate trial on required preferred agents
- Therapy will be denied if no approval criteria are met

Required Documentation

Laboratory Results:
MedWatch Form:

Progress Notes:
Other:

Disposition of Edit

Denial: Exception Code "0160" (Preferred Drug List)
Rule Type: PDL

Default Approval Period

1 year

References

1. Lippincott, Williams, Wilkins. PDR Electronic Library, Montvale NJ; 2020.
2. USPDI, Micromedex; 2020.
3. Facts and Comparisons eAnswers (online); 2020 Clinical Drug Information, LLC.
4. Zakko, S., (2020). Overview of gallstone disease in adults. In S. Grover (Ed.), UpToDate.
5. Evidence-Based Medicine and Fiscal Analysis: "Bile Salt Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; April 2020.
6. Evidence-Based Medicine Analysis: "Bile Salts (Gallstone Solubilizing Agents)", UMKC-DIC; March 2020.
7. Chenodal [package insert]. San Diego, CA. Retrophin Inc; 2015
8. Cholbam [package insert]. Baltimore, MD: Asklepion Pharmaceuticals; 2015.
9. Ocaliva [package insert]. New York, NY. Intercept Pharmaceuticals Inc; 2018.
10. Urso 250 and Urso Forte [package insert]. Irvine, CA: Allergan USA Inc; 2017.
11. Actigall [package insert]. Irvine, CA: Allergan; 2018.

SmartPA PDL Proposal Form

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