

# SmartPA Criteria Proposal

<b>Drug/Drug Class:</b>	Bile Salt Agents PDL Edit
<b>First Implementation Date:</b>	June 23, 2011
<b>Proposed Date:</b>	June 17, 2021
<b>Prepared For:</b>	MO HealthNet
<b>Prepared By:</b>	MO HealthNet/Conduent
<b>Criteria Status:</b>	<input checked="" type="checkbox"/> Existing Criteria <input 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 pharmacologic therapy 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"> <li>Ursodiol</li> </ul>	<ul style="list-style-type: none"> <li>Actigall®</li> <li>Chenodal®</li> <li>Cholbam®</li> <li>Ocaliva®</li> <li>Urso Forte®</li> <li>Urso®</li> </ul>

**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 all approval criteria are not 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. USPDI, Micromedex; 2021.
2. Facts and Comparisons eAnswers (online); 2021 Clinical Drug Information, LLC.
3. Zakko, S., (2020). Overview of gallstone disease in adults. In S. Grover (Ed.), UpToDate.
4. Evidence-Based Medicine and Fiscal Analysis: "Bile Salt Agents – Therapeutic Class Review", Conduent Business Services, L.L.C., Richmond, VA; June 2021.
5. Evidence-Based Medicine Analysis: "Bile Salts (Gallstone Solubilizing Agents)", UMKC-DIC; May 2021.
6. Chenodal [package insert]. San Diego, CA. Retrophin Inc; December 2020.
7. Cholbam [package insert]. San Diego, CA: Manchester Pharmaceuticals, Inc.; October 2020.
8. Ocaliva [package insert]. New York, NY. Intercept Pharmaceuticals Inc; February 2020.
9. Urso 250 and Urso Forte [package insert]. Madison, NJ: Allergan USA, Inc; May 2021.
10. Actigall [package insert]. Irvine, CA: Allergan; May 2018.