Pharmacy Medical Necessity Guidelines: Cholbam® (cholic acid)

Effective: April 14, 2020

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	√
Pharmacy (RX) or Medical (MED) Benefit	Rx	Department to Review	RXUM

These pharmacy medical necessity guidelines apply to the following:

Commercial Products

☐ Tufts Health Plan Commercial products – large group plans
☐ Tufts Health Plan Commercial products – small group and individual plans
☐ Tufts Health Freedom Plan products – large group plans
☐ Tufts Health Freedom Plan products – small group plans
- CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Tufts Health Public Plans Products

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan

Fax Numbers:
RXUM: 617.673.0988

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Cholbam (cholic acid) is a bile acid indicated for:

- Treatment of bile acid synthesis disorders due to single enzyme defects.
- Adjunctive treatment of peroxisomal disorders including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decreased fat soluble vitamin absorption.

COVERAGE GUIDELINES

The plan may authorize coverage of Cholbam (cholic acid) for Members when **all** of the following criteria are met:

Bile acid synthesis disorders

1. Documented diagnosis of bile acid synthesis disorders due to single enzyme defects

Peroxisomal disorders

1. Documented diagnosis of peroxisomal disorders; including Zellweger spectrum disorders in patients who exhibit manifestations of liver disease, steatorrhea or complications from decrease fat soluble vitamin absorption

AND

2. Documentation Cholbam (cholic acid) will be used as adjunctive therapy

LIMITATIONS

None

CODES

None

REFERENCES

1. Cholbam (cholic acid) [prescribing information]. San Diego, CA. Manchester Pharmaceuticals, Inc.; Mar 2015.
2. Gonzales E, Gerhardt MF, Fabre M, et al. Oral cholic acid for hereditary defects of primary bile acid synthesis: a safe and effective long-term therapy. *Gastroenterology.* 2009 Oct;137(4):1310-20.
3. Gould SJ, Valle D. The genetics and cell biology of the peroxisome biogenesis disorders. *Trends Genet*. 2000 Aug;16(8):340-5.
4. Moser AB, Rasmussen M, Naidu S, et al. Phenotype of patients with peroxisomal disorders subdivided into sixteen complementation groups. *J Pediatr*. 1995 Jul;127(1):13-22.
5. Poll-The BT, Gootjes J, Duran M, et al. Peroxisome biogenesis disorders with prolonged survival: phenotypic expression in a cohort of 31 patients. *Am J Med Genet A.* 2004 May 1;126A(4):333-8.

6. Sundaram SS, Bove KE, Lovell MA, et al. Mechanisms of disease: inborn errors of bile acid synthesis. *Nat Clin Pract Gastroenterol Hepatol.* 2008 Aug;5(8):456-68.

APPROVAL HISTORY

July 14, 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
1. January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
2. July 12, 2016: No changes. Effective July 12, 2016 Medical Necessity Guideline applies to Tufts Health Together.
3. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
4. July 11, 2017: No changes
5. June 12, 2018: No changes
6. November 12, 2019: No changes.
7. April 14, 2020: Effective March 30, 2020, PA no longer required for Commercial and Direct Plans. MNG only applies to MA and RITogether plans.

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.