Pharmacy Medical Necessity Guidelines: Welchol® (colesevelam) tablets

Effective: May 12, 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

Bile acid sequestrants (BAS) are one of several available classes of lipid altering agents and are effective in people with mild to moderate elevations in low-density lipoprotein cholesterol (LDL-C). Available BAS products include cholestyramine, colestipol, and colesevelam. Reductions in LDL-C with BAS range between 10 to 15% with moderate doses. Colesevelam has also demonstrated an ability to lower hemoglobin A1C (by 0.5%) in patients with hypercholesterolemia and type 2 diabetes mellitus. The BAS can be administered in combination with HMG-CoA reductase inhibitors (statins) and nicotinic acid. Use of BAS is often limited by gastrointestinal side effects including nausea, bloating, cramping, and an increase in liver enzymes. Colesevelam may be less likely to cause gastrointestinal side effects.

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Colesevelam is a BAS indicated as adjunct to diet and exercise to:

- Reduce elevated LDL-C in adults with primary hyperlipidemia
- Reduce LDL-C levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia as monotherapy or in combination with a statin after failing an adequate trial of diet therapy
- Improve glycemic control in adults with type 2 diabetes mellitus

Colesevelam tablets should not be used for glycemic control in type 1 diabetes or for treating diabetic ketoacidosis. The effect of colesevelam on morbidity and mortality has not been determined. Colesevelam tablets have not been studied in type 2 diabetes in combination with a dipeptidyl peptidase 4 inhibitor; in Fredrickson Type I, III, IV, and V dyslipidemias; or in children younger than 10 years of age or in pre-menarchal girls.

COVERAGE GUIDELINES

The plan may authorize coverage of colesevelam tablets for Members, when **all** of the following criteria are met:

1. Documented trial and failure of at least one formulation of cholestyramine AND colestipol

OR

2. Provider documentation of intolerance to or clinical inappropriateness of therapy with cholestyramine AND colestipol

LIMITATIONS

1. Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria

CODES

None

REFERENCES

1. Davidson MH, Dillon MA, Gordon B, et al. Colesevelam hydrochloride (cholestagel): a new, potent bile acid sequestrant associated with a low incidence of gastrointestinal side effects. Arch Intern Med. 1999;159(16):1893.
2. Insull W Jr, Toth P, Mullican W, et al. Effectiveness of colesevelam hydrochloride in decreasing LDL cholesterol in patients with primary hypercholesterolemia: a 24-week randomized controlled trial. Mayo Clin Proc. 2001;76(10):971.
3. Welchol (colesevelam tablets) [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; September 2019.

APPROVAL HISTORY

June 14, 2016: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. May 9, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether.
2. November 14, 2017: No changes.
3. November 13, 2018: Administrative changes made to template.
4. August 13, 2019: Administrative update, added "Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria" to the limitations section of the MNG.
5. May 12, 2020: No changes.

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.

Provider Services