Pharmacy Medical Necessity Guidelines: HMG-CoA Reductase Inhibitors

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

Ezallor (rosuvastatin) capsule is indicated for:
- Adult patients with hypertriglyceridemia as an adjunct to diet
- Adult patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet
- Adult patients with homozygous familial hypercholesterolemia to reduce familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB.
- Limitations: Ezallor has not been studied in Fredrickson Type I and V dyslipidemia

For patients who have difficulty swallowing capsules, Ezallor can be opened and the granules inside can be emptied it one teaspoon of applesauce. The granules with applesauce must be swallowed immediately without chewing.

FloLipid oral suspension (simvastation) is indicated for:
- Reducing the risk of total mortality by reducing CHD deaths, reducing the risk of non-fatal MI and stroke, and reducing the need for coronary and non-coronary revascularization procedures in patients at high risk of coronary events because of existing coronary heart disease, diabetes, peripheral vessel disease, history of stroke or other cerebrovascular disease
- Reduce elevated total-C, LDL-C, Apo B, and TG, and increase HDL-C in patients with primary hyperlipidemia (Fredrickson type IIa, heterozygous familial and nonfamilial) or mixed dyslipidemia (Fredrickson type IIb)
- Reduce elevated TG in patients with hypertriglyceridemia (Fredrickson type IV hyperlipidemia)
- Reduce elevated TG and VLDL-C in patients with primary dysbetalipoproteinemia (Fredrickson type III hyperlipidemia)
- Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) as an adjunct to other lipid-lowering treatments (e.g., LDL apheresis) or if such treatments are unavailable
- Adjunct to diet to reduce total-C, LDL-C, and Apo B levels in adolescents 10 to 17 years of age with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy

Lescol (fluvastatin) and Lescol XL (fluvastatin) is indicated to:
- Reduce elevated total cholesterol, LDL-C, ApoB, and triglycerides and to increase HDL-C in adult patients with hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia
- Reduce elevated total cholesterol, LDL-C, and Apo B levels in boys and post-menarchal girls, 10 to 16 years of age, with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy

- Reduce the risk of undergoing revascularization procedures in patients with clinically evident coronary heart disease
- Slow the progression of atherosclerosis in patients with coronary heart disease
- Limitations: Neither Lescol (fluvastatin) nor Lescol XL (fluvastatin extended-release) have been studied in conditions where the major abnormality is elevation of chylomicrons, VLDL, or IDL (i.e., hyperlipoproteinemia Types I, III, IV, or V).

Livalo (pitavastatin calcium) and Zypitamag (pitavastatin calcium) are indicated for:
- Primary hyperlipidemia and mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (apoB), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).
- Livalo is also approved for pediatric patients aged 8 years and older with heterozygous family hypercholesterolemia (HeFH) to reduce elevated TC, LDL-C, and ApoB.
- Limitations: Doses greater than 4 mg once daily were associated with an increased risk for severe myopathy in premarketing clinical studies. Do not exceed 4 mg once daily dosing. The effect of Livalo (pitavastatin calcium) and Zypitamag (pitavastatin magnesium) on cardiovascular morbidity and mortality has not been determined. Livalo (pitavastatin calcium) and Zypitamag (pitavastatin magnesium) have not been studied in Fredrickson Type I, III, and V dyslipidemias

Relative LDL-lowering Efficacy of Statin Therapies*

%↓ LDL-C	Atorvastatin	Fluvastatin	Pitavastatin	Lovastatin	Pravastatin	Rosuvastatin	Simvastatin
30%	-----	40 mg	1 mg	20 mg	20 mg	-----	10 mg
38%	10 mg	80 mg	2 mg	40 or 80 mg	40 mg	-----	20 mg
41%	20 mg	-----	4 mg	80 mg	80 mg	5 mg	40 mg
47%	40 mg	-----		-----	-----	10 mg	80 mg
55%	80 mg	-----		-----	-----	20 mg	-----
63%		-----		-----	-----	40 mg	-----

*Adapted from:
http://www.fda.gov/Drugs/DrugSafety/ucm256581.htm#Simvastatin_Dose_Limitations

COVERAGE GUIDELINES

The plan may authorize coverage of a non-preferred HMG-CoA Reductase Inhibitor for Members when **all** of the following criteria are met:

Fluvastatin, Livalo (pitavastatin calcium), and Zypitamag (pitavastatin magnesium)

1. The Member tried and failed therapy with at least two alternative statins, or the provider indicates clinical inappropriateness of treatment with at least two alternative statins

FloLipid (simvastatin) oral suspension

1. The Member has demonstrated an inadequate response to OR is unable to tolerate an adequate trial with two generic cholesterol agents, one of which should be simvastatin tablets

OR

1. Documented evidence of dysphagia or difficulty swallowing tablets

Ezallor (rosuvastatin)

1. The Member tried and failed therapy with rosuvastatin and at least one additional generic statin or the prescriber submits documentation that the member has difficulty swallowing tablets and capsules

LIMITATIONS

1. Coverage of Ezallor, fluvastatin and Livalo is limited to 30 capsules/tablets per month.
2. Requests for brand-name products, which have AB-rated generics, will be also reviewed according to Brand Name criteria.

CODES

None

REFERENCES

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APPROVAL HISTORY

September 8, 2004: Reviewed by Pharmacy & Therapeutics Committee

Subsequent endorsement date(s) and changes made:

1. July 19, 2012: No changes.
2. July 8, 2014: Criteria for Simcor removed due to non-covered formulary status.
3. March 10, 2015: Criteria modified and strength specific for Crestor; approval duration modified to one year.
4. September 16, 2015: Approval duration modified to life of plan; removed renewal criteria; removed criteria related to LDL-lowering goals.
5. January 1, 2016: Administrative change to rebranded template.
6. June 14, 2016: Added limitation #2 "Requests for brand-name products, which have AB-rated generics, will be reviewing according to Brand Name criteria."
7. May 9, 2017: Administrative update, Adding Tufts Health RITogether to the template.
8. June 13, 2017: No changes.
9. May 8, 2018: Added Zypitamag (pitavastatin magnesium) to the Medical Necessity Guideline.
10. March 12, 2019: Effective 4/1/2019, removed criteria for rosuvastatin, it is now covered. Administrative changes made to template.
11. August 13, 2019: Added Ezallor (rosuvastatin) capsule to the Medical Necessity Guideline.
12. February 11, 2020: No changes.
13. April 14, 2020: Effective 4/14/20, added FloLipid to the MNG.

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.