Pharmacy Medical Necessity Guidelines: HMG-CoA Reductase Inhibitors

Effective: April 1, 2019

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

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

Lescol (fluvastatin) and Lescol XL (fluvastatin) is indicated for:
- 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).
- 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*

<table>
<thead>
<tr>
<th>%↓ LDL-C</th>
<th>Atorvastatin</th>
<th>Fluvastatin</th>
<th>Pitavastatin</th>
<th>Lovastatin</th>
<th>Pravastatin</th>
<th>Rosuvastatin</th>
<th>Simvastatin</th>
</tr>
</thead>
<tbody>
<tr>
<td>30%</td>
<td>-----</td>
<td>40 mg</td>
<td>1 mg</td>
<td>20 mg</td>
<td>20 mg</td>
<td>-----</td>
<td>10 mg</td>
</tr>
<tr>
<td>38%</td>
<td>10 mg</td>
<td>80 mg</td>
<td>2 mg</td>
<td>40 or 80 mg</td>
<td>40 mg</td>
<td>-----</td>
<td>20 mg</td>
</tr>
<tr>
<td>41%</td>
<td>20 mg</td>
<td>-----</td>
<td>4 mg</td>
<td>80 mg</td>
<td>80 mg</td>
<td>5 mg</td>
<td>40 mg</td>
</tr>
<tr>
<td>47%</td>
<td>40 mg</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>10 mg</td>
<td>80 mg</td>
</tr>
<tr>
<td>55%</td>
<td>80 mg</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>20 mg</td>
<td>-----</td>
<td>-----</td>
</tr>
<tr>
<td>63%</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>40 mg</td>
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<td>-----</td>
</tr>
</tbody>
</table>

*Adapted from: [fda.gov/Drugs/DrugSafety/ucm256581.htm#Simvastatin_Dose_Limitations](https://fda.gov/Drugs/DrugSafety/ucm256581.htm#Simvastatin_Dose_Limitations)
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

LIMITATIONS
1. Coverage of fluvastatin and Livalo is limited to 30 capsules/tablets per month.
2. Requests for brand-name products, which have AB-rated generics, will be reviewing according to Non-covered Medications criteria.

CODES
None

REFERENCES
12. Lescol (fluvastatin) and Lescol XL (fluvastatin extended-release) [prescribing information]. East Hanover, NJ: Novartis; August 2017.
13. Livalo (pitavastatin calcium) [prescribing information]. Kowa Pharmaceuticals America, Inc: Montgomery, AL; December 2016.

21. Zypitamag (pitavastatin magnesium) [prescribing information]. Medicure; Somerset, NJ; December 2018.

APPROVAL HISTORY

September 8, 2004: Reviewed by Pharmacy & Therapeutics Committee

Subsequent endorsement date(s) and changes made:
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.
10. March 12, 2019: Effective 4/1/2019, removed criteria for rosuvastatin, it is now covered. Administrative changes made to template.

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