HMG-CoA Reductase Inhibitors
Crestor (rosuvastatin); Lescol/Lescol XL (fluvastatin); Livalo (pitavastatin)
Effective: 10/1/15

<table>
<thead>
<tr>
<th>Clinical Documentation and Prior Authorization Required</th>
<th>Type of Review – Case Management</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not Covered</td>
<td>Type of Review – Clinical Review</td>
</tr>
<tr>
<td>Pharmacy (RX) or Medical (MED) Benefit</td>
<td>Fax: 617-673-0988</td>
</tr>
</tbody>
</table>

OVERVIEW
FDA-APPROVED INDICATIONS
Pitavastatin (Livalo) is indicated for patients with primary hyperlipidemia or mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).

Rosuvastatin (Crestor) is indicated for:
- Patients with primary hyperlipidemia and mixed dyslipidemias as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C, and TG levels and to increase HDL-C.
- Patients with hypertriglyceridemia as an adjunct to diet.
- Patients with primary dysbetalipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet.
- Patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C and ApoB.
- Slowing the progression of atherosclerosis as part of a treatment strategy to lower total-C and LDL-C as an adjunct to diet.
- Pediatric patients 10 to 17 years of age with heterozygous familial hypercholesterolemia (HeFH) to reduce elevated total-C, LDL-C, and ApoB after failing an adequate trial of dietary therapy.
- Risk reduction of MI, stroke, and arterial revascularization procedures in patients without clinically evident CHD, but with multiple risk factors.

Fluvastatin (Lescol/Lescol XL) is indicated as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, and TG levels in patients with primary hyperlipidemia and mixed hyperlipidemia (Frederickson Type IIa and IIb) whose response to dietary restriction of saturated date and cholesterol and other nonpharmacological measures has not been adequate.

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>-----</td>
<td>20 mg</td>
<td>-----</td>
</tr>
<tr>
<td>63%</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>40 mg</td>
<td>-----</td>
</tr>
</tbody>
</table>

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

PHARMACY COVERAGE GUIDELINES
Tufts Health Plan – Network Health may authorize coverage of a non-preferred HMG-CoA Reductase Inhibitor for members when all the following criteria for a particular regimen are met and limitations do not apply:
Pharmacy Medication Request Guidelines:
HMG-CoA Reductase Inhibitors

For Crestor 5 mg or 10 mg,
- The member requires moderate LDL lowering (30% to 50% reduction).
- The member tried and failed therapy with all of the following, or the provider indicates clinical inappropriateness of treatment* with all of the following:
  - Simvastatin ≥ 40 mg
  - Pravastatin ≥ 40 mg
  - Atorvastatin ≥ 20 mg.

For Crestor 20 mg or 40 mg,
- The member requires high LDL lowering (> 50% reduction).
- The member tried and failed therapy with, or the provider indicates clinical inappropriateness of treatment* with atorvastatin 80 mg.

For fluvastatin (Lescol) or Livalo,
- The member tried and failed therapy with at least two of the preferred statins with similar LDL reduction (moderate or low intensity), or the provider indicates clinical inappropriateness of treatment* with at least two of the preferred statins with similar LDL reduction (moderate or low intensity).

Upon renewal,
- The member has had an office visit and has been re-assessed for this condition within the past year, and continued therapy with this medication is considered medically necessary.

*Clinical inappropriateness of treatment may include potential drug interactions, contraindication, intolerance, or unachievable therapeutic goal.

**Limitations**
- The coverage is limited to one tablet/capsule per day.
- The length of approval will be for 2 years; subsequent approval will require a new authorization.

**Codes**
None

**References**
5. Simcor [prescribing information]. AbbVie, Inc: North Chicago, IL; March 2013.


APPROVAL HISTORY

- 09/08/2004: Reviewed by the Pharmacy and Therapeutics Committee.
- 07/19/2012: Reviewed by the Pharmacy and Therapeutics Committee.
- 07/08/2014: Reviewed by the Pharmacy and Therapeutics Committee; criteria for Simcor removed due to non-covered formulary status.
- 03/10/2015: Reviewed by the Pharmacy and Therapeutics Committee; criteria modified and strength specific for Crestor; approval duration modified to one year.
- 07/14/2015: Reviewed by the Pharmacy and Therapeutics Committee; approval duration modified to 2 years.

BACKGROUND, PRODUCT, AND DISCLAIMER INFORMATION

Pharmacy Medication Request Guidelines have been developed for determining coverage for Tufts Health Plan – Network Health benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. They are used in conjunction with the applicable Member Handbook and in coordination with the member’s physician(s). Pharmacy Medication Request 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 Tufts Health Plan – Network Health service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. Tufts Health Plan – Network Health reviews Pharmacy Medication Request Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.
Pharmacy Medication Request Guidelines apply to all insured offerings unless otherwise noted in this policy or the applicable Member Handbook. Check the applicable Preferred Drug List (formulary) in the pharmacy section of our website to determine if the drug requires you to get prior authorization.

For Tufts Health Unify (Medicare-Medicaid One Care for people ages 21 – 64), please refer to the Tufts Health Unify Prior Authorization Medical Necessity Guidelines.

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.