Pharmacy Medical Necessity Guidelines: Crestor® (rosuvastatin)

Effective: November 1, 2017

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

Fax Numbers:
RXUM: 617.673.0988

This Pharmacy Medical Necessity Guideline applies to the following:

Tufts Health Plan Commercial Plans
✓ Tufts Health Plan Commercial Plans – large group plans
✓ Tufts Health Plan Commercial Plans – small group and individual plans

Tufts Health Public Plans
✓ Tufts Health Direct – Health Connector
☐ Tufts Health Together – A MassHealth Plan
☐ Tufts Health RITogether – A RIte Care + Rhody Health Partners Plan

Tufts Health Freedom Plan products
✓ Tufts Health Freedom Plan – large group plans
✓ Tufts Health Freedom Plan – small group plans

Note: For Tufts Health Plan Medicare Preferred Members, please refer to the Tufts Health Plan Medicare Preferred Step Therapy Criteria. Background, applicable product and disclaimer information can be found on the last page.

OVERVIEW

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS
Crestor (rosuvastatin) is an HMG-CoA reductase inhibitor indicated for:

Hyperlipidemia and Mixed Dyslipidemia
Adjunctive therapy to diet to reduce elevated total cholesterol (total-C), low density lipoprotein cholesterol (LDL-C), apolipoprotein B (ApoB), non-high-density lipoprotein cholesterol (nonHDL-C), and triglycerides (TG) and to increase high-density lipoprotein cholesterol (HDL-C) in adult patients with primary hyperlipidemia or mixed dyslipidemia. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol when response to diet and nonpharmacological interventions alone has been inadequate.

Pediatric Patients 8 to 17 years of age with Heterozygous Familial Hypercholesterolemia (HeFH)
Adjunct to diet to reduce Total-C, LDL-C and ApoB levels in children and adolescents 8 to 17 years of age with HeFH if after an adequate trial of diet therapy the following findings are present: LDL-C >190 mg/dL and there is a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors.

Hypertriglyceridemia
Adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia.

Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia)
Adjunct to diet for the treatment of patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia).

Homozygous Familial Hypercholesterolemia
Adjunctive therapy to other lipid-lowering treatments (e.g., LDL apheresis) or alone if such treatments are unavailable to reduce LDL-C, Total-C, and ApoB in adult patients with homozygous familial hypercholesterolemia.

Slowing of the Progression of Atherosclerosis
Adjunctive therapy to diet to slow the progression of atherosclerosis in adult patients as part of a treatment strategy to lower Total-C and LDL-C to target levels.

Primary Prevention of Cardiovascular Disease
In individuals without clinically evident coronary heart disease but with an increased risk of cardiovascular disease based on age ≥50 years old in men and ≥60 years old in women, hsCRP ≥ 2 mg/L, and the presence of at least one additional CVD risk factor such as hypertension, low HDL-C,
smoking, or a family history of premature coronary heart disease, Crestor (rosuvastatin) is indicated to reduce the risk of stroke, reduce the risk of myocardial infarction, and reduce the risk of arterial revascularization procedures.

Crestor (rosuvastatin) has not been studied in Fredrickson Type I 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>10 mg</td>
<td>40 mg</td>
<td>1 mg</td>
<td>10 mg</td>
<td>20 mg</td>
<td>40 mg</td>
<td>-----</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>10 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>80 mg</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>80 mg</td>
<td>-----</td>
<td>20 mg</td>
<td>-----</td>
</tr>
<tr>
<td>63%</td>
<td>-----</td>
<td>-----</td>
<td>-----</td>
<td>80 mg</td>
<td>-----</td>
<td>40 mg</td>
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</tr>
</tbody>
</table>

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

### COVERAGE GUIDELINES

The plan may authorize coverage of rosuvastatin for Members when all of the following criteria are met:

**Rosuvastatin 5 mg and 10 mg:**
1. The Member has tried ALL of the following drugs and could not tolerate treatment due to adverse effects or there was inadequate response despite compliance with maximum tolerable doses:
   a. Simvastatin ≥ 20 mg
   b. Pravastatin ≥ 40 mg
   c. Atorvastatin ≥ 10 mg

**Rosuvastatin 20 mg and 40 mg:**
1. The Member has tried atorvastatin 40 mg or 80 mg and was unable to tolerate treatment due to adverse effects or there was inadequate response despite compliance with maximum tolerable doses

### LIMITATIONS
1. Crestor is not covered for all COMM formularies. If requesting brand name Crestor please refer to the medical necessity guidelines for Non-Covered Drugs with Suggested Alternatives.
2. Rosuvastatin 5 mg and 10 mg is limited to a quantity of 90 tablets per 90 days.

### CODES
None

### REFERENCES

APPROVAL HISTORY
January 2015: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:
- July 14, 2015: Removed the criteria requiring documentation of moderate to high LDL lowering.
- January 1, 2016: Administrative change to rebranded template applicable to Tufts Health Direct.
- June 14, 2016: Updated the approval criteria for brand Crestor due to the launch of the generic as part of normal course of business.
- October 17, 2017: Added quantity limitation for 5 mg and 10 mg rosuvastatin tablets.

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. They are used in conjunction with a Member’s benefit document and in coordination with the Member’s physician(s). 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.

This Pharmacy Medical Necessity Guideline does not apply to Uniformed Services Family Health Plan Members or to certain delegated service arrangements. Unless otherwise noted in the Member’s benefit document or applicable Pharmacy Medical Necessity Guideline, Pharmacy Medical Necessity Guidelines do not apply to CareLinkSM Members. For self-insured plans, drug coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a coverage guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. Applicable state or federal mandates will take precedence.

For Tufts Health Plan Medicare Preferred, please refer to Tufts Health Plan Medicare Preferred Prior Authorization Criteria.

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.