Clinical Policy: Rosuvastatin (Crestor)

Reference Number: CP.PST.20
Effective Date: 11.28.17 Revision Log
Last Review Date:
Line of Business: Medicaid

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Rosuvastatin (Crestor®) is an HMG Co-A reductase inhibitor.

FDA Approved Indication(s)
Crestor is indicated for the treatment of:

- Adult patients with primary hyperlipidemia and mixed dyslipidemia as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C, and TG levels and to increase HDL-C
- Pediatric patients 8 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 diet therapy
- Pediatric patients 7 to 17 years of age with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, nonHDL-C and ApoB as an adjunct to diet, either alone or with other lipid-lowering treatments
- 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 (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
- Risk reduction of MI, stroke, and arterial revascularization procedures in patients without clinically evident CHD, but with multiple risk factors

Limitations of use: Crestor has not been studied in Fredrickson Type I and V dyslipidemias

Policy/Criteria
Provider must submit documentation (which may include office chart notes and lab results) supporting that member has met all approval criteria

It is the policy of health plans affiliated with Centene Corporation® that Crestor is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Step Therapy for Crestor (must meet all)**:**

1. Failure of atorvastatin or simvastatin, unless contraindicated or clinically significant adverse effects are experienced;
2. Dose does not exceed 40 mg per day (1 tablet/day).

Approval duration: 12 months

II. Continued Therapy

A. Step Therapy for Crestor (must meet all)**:**

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 40 mg per day (1 tablet/day).

Approval duration: 12 months

III. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

Apo B: apolipoprotein B
FDA: Food and Drug Administration
HoFH: homozygous familial hypercholesterolemia
LDL-C: low-density lipoprotein cholesterol
non-HDL-C: non-high-density lipoprotein cholesterol
total-C: total cholesterol

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Atorvastatin (Lipitor®)	10 to 80 mg per day Pediatric patients (10 to 17 years): 10 to 20 mg per day	80 mg per day
Simvastatin (Zocor®)	5 to 40 mg per day Adolescents (10-17 years) with HeFH: 10 mg per day	40 mg per day for most patients; 80 mg/day for patients already taking 80 mg/day chronically without evidence of myopathy Adolescents: 40 mg per day

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

IV. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
All Indications	5-40 mg once daily	40 mg only for patients not reaching LDL-C goal with 20 mg

V. Product Availability
Tablets: 5 mg, 10 mg, 20 mg, and 40 mg

VI. Workflow Document
Not Applicable

VII. References
1. Crestor Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP: August 2017. Available at https://www.crestor.com/. Accessed January 4, 2018.
2. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2017. Available at: http://www.clinicalpharmacology-ip.com/.
3. Lloyd-Jones DM, Morris PB, Ballantyne CM, et al. 2016 ACC expert consensus decision pathway on the role of non-statin therapies for LDL-cholesterol lowering in the management of atherosclerotic cardiovascular disease risk: a report of the American College of Cardiology Task Force on Clinical Expert Consensus Documents. J Am Coll Cardiol 2016;68:92–125.
4. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology Guidelines for Management of Dyslipidemia and Prevention of Cardiovascular Disease. Endocr Pract. 2017 Apr;23(Suppl 2):1-87.
5. Third Report of the National Cholesterol Educational Program (NCEP) Expert Panel on Detection, Evaluation and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). https://www.nhlbi.nih.gov/files/docs/guidelines/atp3xsum.pdf. Accessed December 1, 2016.
6. Stone NJ, Robinson J, Lichtenstein AH, Bairey Merz CN, Blum CB, Eckel RH, Goldberg AC, Gordon D, Levy D, Lloyd-Jones DM, McBride P, Schwartz JS, Shero ST, Smith SC Jr, Watson K, Wilson PWF. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerotic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation. 2013;00:000–000.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	11.28.17	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health

plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.