

STEP THERAPY CRITERIA

BRAND NAME (generic)

(rosuvastatin 5 mg and 10 mg only) (generic only)

Status: CVS Caremark Criteria

Type: Initial Step Therapy; Post Step Therapy Prior Authorization

POLICY

FDA-APPROVED INDICATIONS

Rosuvastatin

Hyperlipidemia and Mixed Dyslipidemia

Rosuvastatin is indicated as adjunctive therapy to diet to reduce elevated Total-C, LDL-C, ApoB, nonHDL-C, and triglycerides and to increase 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 with Familial Hypercholesterolemia

Rosuvastatin is indicated as adjunct to diet to:

- Reduce Total-C, LDL-C and ApoB levels in children and adolescents 8 to 17 years of age with heterozygous familial hypercholesterolemia if after an adequate trial of diet therapy the following findings are present: LDC-C > 190 mg/dL, or > 160 mg/dL along with a positive family history of premature cardiovascular disease (CVD) or two or more other CVD risk factors.
- Reduce LDL-C, Total-C, nonHDL-C and ApoB in children and adolescents 7 to 17 years of age with homozygous familial hypercholesterolemia, either alone or with other lipid-lowering treatments (e.g., LDL apheresis).

Hypertriglyceridemia

Rosuvastatin is indicated as adjunctive therapy to diet for the treatment of adult patients with hypertriglyceridemia.

Primary Dysbetalipoproteinemia (Type III Hyperlipoproteinemia)

Rosuvastatin is indicated as an adjunct to diet for the treatment of adult patients with primary dysbetalipoproteinemia (Type III Hyperlipoproteinemia).

Adult Patients with Homozygous Familial Hypercholesterolemia

Rosuvastatin is indicated as 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

Rosuvastatin is indicated as 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 cardiovascular disease risk factor such as hypertension, low HDL-C, smoking, or a family history of premature coronary heart disease, rosuvastatin is indicated to:

- Reduce the risk of stroke
- Reduce the risk of myocardial infarction
- Reduce the risk of arterial revascularization procedures

Limitations of Use

Rosuvastatin has not been studied in Fredrickson Type I and V dyslipidemias.

INITIAL STEP THERAPY for Rosuvastatin 5 mg and 10 mg (generic only)

If the patient is less than 10 years of age OR has filled a prescription for at least a 30-day supply of atorvastatin or simvastatin within the past 180 days under a prescription benefit administered by CVS Caremark, then the requested drug will be paid under that prescription benefit. If the patient does not meet the initial step therapy criteria, then the claim will reject with a message indicating that a prior authorization (PA) is required. The prior authorization criteria would then be applied to requests submitted for evaluation to the PA unit.

COVERAGE CRITERIA

The requested drug will be covered with prior authorization when the following criteria are met:

- The patient has experienced an inadequate treatment response to atorvastatin OR simvastatin
OR
- The patient has experienced an intolerance to atorvastatin OR simvastatin
OR
- The patient has a contraindication that would prohibit a trial of atorvastatin OR simvastatin
OR
- The requested drug is being prescribed for the treatment of homozygous familial hypercholesterolemia in a patient less than 18 years of age

REFERENCES

1. Atorvastatin [package insert]. Iselin, NJ: Biocon Pharma Inc.; May 2019.
2. Crestor [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2018.
3. Rosuvastatin [package insert]. Weston, FL: Apotex Corp; January 2019.
4. Simvastatin [package insert]. Durham, NC: Accord Healthcare, Inc.; April 2019.
5. Lexicomp Online, AHFS DI (Adult and Pediatric) Online. Hudson, OH: Wolters Kluwer Clinical Drug Information, Inc. <http://online.lexi.com/>. Accessed November 2019.
6. Micromedex (electronic version). Truven Health Analytics, Greenwood Village, Colorado, USA. <http://www.micromedexsolutions.com/>. Accessed November 2019.
7. Grundy SM, Stone NJ, Bailey AL, et al. 2018
AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA Guideline on the Management of Blood Cholesterol. *Circulation* 2019; 139:e1082-1143.