STEP THERAPY CRITERIA

BRAND NAME
(generic)

LIVALO
(pitavastatin calcium)

NIKITA
(pitavastatin sodium)

(rosuvastatin 5MG AND 10MG ONLY) (GENERIC ONLY)

ZYPITAMAG
(pitavastatin magnesium)

Status: CVS Caremark Criteria
Type: Initial Step Therapy; Post Step Therapy Prior Authorization

Policy

FDA-APPROVED INDICATIONS
Livalo
Drug therapy should be one component of multiple-risk-factor intervention in individuals who require modifications of their lipid profile. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate.

Hyperlipidemia and Mixed Dyslipidemia
Livalo (pitavastatin) is indicated as 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 HDL-C in adult patients with primary hyperlipidemia and dyslipidemia.

Limitations of Use
Doses of Livalo (pitavastatin) 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 of Livalo (pitavastatin).

The effect of Livalo (pitavastatin) on cardiovascular morbidity and mortality has not been determined.

Livalo (pitavastatin) has not been studied in Fredrickson Type I, III, and V dyslipidemias.

Nikita
Drug therapy should be one component of multiple-risk-factor intervention in individuals who require modifications of their lipid profile. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate.

Primary Hyperlipidemia and Mixed Dyslipidemia
Nikita (pitavastatin) is indicated 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 HDL-C in adult patients with primary hyperlipidemia or mixed lipidemia.

Limitations of Use
Doses of Nikita (pitavastatin) 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 of Nikita (pitavastatin).

The effect of Nikita (pitavastatin) on cardiovascular morbidity and mortality has not been determined.

Nikita (pitavastatin) has not been studied in Fredrickson Type I, III, and V dyslipidemias.

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.

Zypitamag

Drug therapy should be one component of multiple-risk-factor intervention in individuals who require modifications of their lipid profile. Lipid-altering agents should be used in addition to a diet restricted in saturated fat and cholesterol only when the response to diet and other nonpharmacological measures has been inadequate.

Primary Hyperlipidemia and Mixed Dyslipidemia

Zypitamag (pitavastatin) is indicated 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 HDL-C in adult patients with primary hyperlipidemia or mixed lipidemia.

Limitations of Use
Doses of Zypitamag (pitavastatin) 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 of Zypitamag (pitavastatin).

The effect of Zypitamag (pitavastatin) on cardiovascular morbidity and mortality has not been determined.

Zypitamag (pitavastatin) has not been studied in Fredrickson Type I, III, and V dyslipidemias.

INITIAL STEP THERAPY for Rosuvastatin
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.

INITIAL STEP THERAPY for Livalo, Nikita, Zypitamag
If the patient 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, intolerance or contraindication to atorvastatin OR simvastatin
  OR
- The requested drug is rosuvastatin 5 mg or 10 mg
  AND
  - The requested drug is being used for the treatment of homozygous familial hypercholesterolemia in a patient less than 18 years of age

REFERENCES

1. Crestor [package insert]. Wilmington, DE: AstraZeneca; August. 2017
2. Rosuvastatin [package insert]. Parsippany, NJ: Actavis Pharma, Inc.; January 2018
3. Livalo [package insert]. Montgomery, AL; Kowa Pharmaceuticals America, Inc.; December 2016
4. Nikita [package insert]. Baltimore, MD; Lupin Pharmaceuticals, Inc.; August 2017
5. Zypitamag [package insert]. Somerset, NJ; Medicure; March 2018
6. Atorvastatin [package insert]. Weston, FL: Apotex Corp.; January 2018
7. Simvastatin [package insert]. North Wales, PA: Teva Pharmaceuticals USA, Inc.; March 2017
8. AHFS DI (Adult and Pediatric) [database online]. Hudson, OH: Lexi-Comp, Inc.; http://online.lexi.com/lco/action/index/dataset/complete_ashp [available with subscription]. Accessed March 2018.
9. Micromedex Solutions [database online]. Greenwood Village, CO: Truven Health Analytics Inc. Updated periodically. www.micromedexsolutions.com [available with subscription]. Accessed March 2018.
10. Stone NJ, Robinson JG, Lichtenstein AH, et al. 2013 ACC/AHA Guideline on the treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults. *Circulation* 2014;129[suppl2]:S1-S45.

