Commercial/Healthcare Exchange PA Criteria

Effective: 6/9/2021

Prior Authorization: ROSZET (rosuvastatin and ezetimibe)

Products Affected: ROSZET (rosuvastatin and ezetimibe) tablets, for oral use

Medication Description:
ROSZET tablets contain rosuvastatin calcium and ezetimibe. Rosuvastatin is a 3-hydroxy-3 methylglutaryl coenzyme A (HMG CoA)-reductase inhibitor. Ezetimibe is a dietary cholesterol absorption inhibitor.

Rosuvastatin: Rosuvastatin is an inhibitor of HMG CoA-reductase, the rate-limiting enzyme that converts 3-hydroxy3-methylglutaryl coenzyme A to mevalonate, a precursor of cholesterol. In in vivo and in vitro studies, rosuvastatin produces its lipid-modifying effects in two ways. First, it increases the number of hepatic LDL receptors on the cell-surface to enhance uptake and catabolism of LDL. Second, rosuvastatin inhibits hepatic synthesis of VLDL, which reduces the total number of VLDL and LDL particles.

Ezetimibe: The molecular target of ezetimibe is the sterol transporter, Niemann-Pick C1-Like 1 (NPC1L1), which is involved in the intestinal uptake of cholesterol and phytosterols. Ezetimibe localizes at the brush border of the small intestine and inhibits the absorption of cholesterol, leading to a decrease in the delivery of intestinal cholesterol to the liver. This causes a reduction of hepatic cholesterol stores and an increase in clearance of cholesterol from the blood.

Covered Uses:

- Familial hypercholesterolemia - homozygous, Alone or Adjunct to Other LDL-C Lowering Therapies
- Hyperlipidemia, Primary nonfamilial; Adjunct to Diet

Exclusion Criteria:

- Acute liver failure or decompensated cirrhosis
- Hypersensitivity to rosuvastatin, ezetimibe, or any component of the product

Required Medical Information:

1. Diagnosis
2. Medications tried and failed

Age Restrictions: 18 years of age or older.

Prescriber Restrictions: N/A

Coverage Duration: 1 year for initial and continuation of therapy

Other Criteria:

I. Initial Approval Criteria
(must meet all):

A. Familial hypercholesterolemia:

1. Patient has diagnosis of homozygous familial hypercholesterolemia (HoFH); AND
2. Patient is 18 years of age or older; AND
3. The medication will be used alone or adjunct to Other LDL-C Lowering Therapies; AND
4. The recommended dose does not exceed 5 mg/10 mg to 40 mg/10 mg once daily; AND
5. LDL-C will be assessed when clinically appropriate; AND
6. Patient has had at least a 60-day trial of a GENERIC statin medication and ezetimibe and did not achieve LDL cholesterol goal. Documentation for all cholesterol lowering medications tried and failed must be provided including (but not limited to) chart notes, prescription claims records, laboratory data, reason for failure of medications tried (e.g. symptoms, frequency, elevated LFTs, CPK. etc).

B. **Hyperlipidemia, Primary nonfamilial:**

1. Patient has diagnosis of primary non-familial hyperlipidemia; AND
2. Patient is 18 years of age or older; AND
3. The medication will be used as an adjunct to diet to reduce low-density lipoprotein cholesterol (LDLC); AND
4. The recommended dose does not exceed 5 mg/10 mg to 40 mg/10 mg once daily; AND
5. LDL-C will be assessed when clinically appropriate; AND
6. Patient has had at least a 60-day trial of a GENERIC statin medication and ezetimibe and did not achieve LDL cholesterol goal. Documentation for all cholesterol lowering medications tried and failed must be provided including (but not limited to) chart notes, prescription claims records, laboratory data, reason for failure of medications tried (e.g. symptoms, frequency, elevated LFTs, CPK. etc).

II. Continued Therapy

1. Member is responding positively to therapy based on laboratory data and chart notes; AND
2. Member has not experienced unacceptable toxicity from the drug (for example hepatotoxicity, rhabdomyolysis, myopathy, proteinuria, hematuria. etc).

References:

1. ROSZET (rosuvastatin and ezetimibe) tablets [Package Insert]. Morristown NJ. Althera Pharmaceuticals LLC. Updated March 2021. Accessed April 29, 2021.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New policy	New policy	All	6/9/2021