MEDICAL MUTUAL®

Drug Policy

Policy:	**Ezetimibe-Containing Products Preferred Step Therapy** **Roszet (ezetimibe/rosuvastatin)** **Vytorin (ezetimibe/simvastatin)** **Zetia (ezetimibe)**	**Annual Review Date:** **04/21/2022** **Last Revised Date:** **04/21/2022**

OVERVIEW

Zetia, an inhibitor of intestinal cholesterol (and related phytosterol) absorption, is indicated as an adjunct to diet to: 1) reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B) and non-high-density lipoprotein cholesterol (non-HDL-C) in patients with primary hyperlipidemia either as monotherapy or in combination with a hydroxy-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor (statin); 2) reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH) in combination with atorvastatin or simvastatin; 3) reduce elevated total-C, LDL-C, apo B, and non-HDL-C in combination with fenofibrate; and 4) reduce elevated sitosterol and campesterol levels in homozygous sitosterolemia (phytosterolemia). Zetia reduces blood cholesterol by inhibiting the absorption of cholesterol by the small intestine. Zetia is available generically. Vytorin (ezetimibe/simvastatin) is a combination product indicated to 1) reduce elevated total cholesterol (total-C), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (apo B), TG, and non-HDL-C, and to increase HDL-C in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia; and 2) reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid-lowering treatments. Vytorin also is available generically.

POLICY STATEMENT

A preferred step therapy program has been developed to encourage the use of a preferred, generic products prior to the use of a non-preferred product. Approval duration is for 1 year.

Automation: A patient with a history of one Step 1 drug within the 365-day look-back period can receive the Step 2 drug.

Preferred products: generic ezetimibe, ezetimibe/simvastatin

Non-Preferred products: Zetia, Vytorin, Roszet

RECOMMENDED AUTHORIZATION CRITERIA

Exceptions for brand name Zetia or Vytorin tablets can be made for those who meet the following criteria.

1. Approve Roszet if the patient has tried one preferred product.

2. Approve Vytorin if the patient has tried ezetimibe/simvastatin AND the brand product is being requested due to a formulation difference in the inactive ingredient(s) between the brand and the generic product which, according to the prescriber, has or would result in a significant allergy or adverse reaction.

3. Approve Zetia if the patient has tried ezetimibe AND the brand product is being requested due to a formulation difference in the inactive ingredient(s) between the brand and the generic product which, according to the prescriber, has or would result in a significant allergy or adverse reaction.

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year (365 days)
B) *Extended Approval:* 1 year (365 days)

Step Therapy Exception Criteria
In certain situations, the patient is not required to trial preferred agents. Approve for 1 year if the patient meets the following (A, B, or C):

A. The patient has an atypical diagnosis and/or unique patient characteristics which prevent use of all preferred agents. If so, please list diagnosis and/or patient characteristics [documentation required]; **OR**
B. The patient has a contraindication to all preferred agents. If so, please list the contraindications to each preferred agent [documentation required]; **OR**
C. The patient is continuing therapy with the requested non-preferred agent after being stable for at least 90 days [verification in prescription claims history required] or, if not available, [verification by prescribing physician required] AND meets ONE of the following:
    1. The patient has at least 130 days of prescription claims history on file and claims history supports that the patient has received the requested non-preferred agent for 90 days within a 130-day look-back period AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product); OR
    2. When 130 days of the patient's prescription claims history file is unavailable for verification, the prescriber must verify that the patient has been receiving the requested non-preferred agent for 90 days AND that the patient has been receiving the requested non-preferred agent via paid claims (i.e. the patient has NOT been receiving samples or coupons or other types of waivers in order to obtain access to the requested non-preferred agent) AND there is no generic equivalent available for the requested nonpreferred product (i.e. AA-rated or AB-rated to the requested nonpreferred product).

Documentation Required: When documentation is required, the prescriber must provide written documentation supporting the trials of these other agents, noted in the criteria as [documentation required]. Documentation should include chart notes, prescription claims records, and/or prescription receipts.

Approval Duration: All approvals for continuation of therapy are provided for 1 year unless noted otherwise below. In cases where the initial approval is authorized in months, 1 month is equal to 30 days.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

- Zetia® tablets [prescribing information]. Whitehouse Station, NJ: Merck; August 2013.
- Vytorin [prescribing information]. Kenilworth, NJ: Merck Sharp & Dohme Corp. February 2018.
- Jellinger PS, Yehuda H, Rosenblit PD. American Association of Clinical Endocrinologist and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease – executive summary. *ACCE 2017*. Available at https://www.aace.com/files/lipid-guidelines.pdf . Accessed on March 20, 2017.
- Stone NJ, Robinson J, Lichtenstein AH, et al. 2013 ACC/AHA guideline on the treatment of blood cholesterol to reduce atherosclerostic cardiovascular risk in adults: a report of the American College of Cardiology/American Heart Association Task Force on Practice guidelines. *Circulation*. 2014;129(25 Suppl 2):S1-45.
- Roszet [prescribing information]. Morristown, NJ: Althera Pharmaceuticals LLC; March 2021.