POLICY AND PROCEDURE

POLICY TITLE: **Vytorin (Ezetimibe/Simvastatin) Step Therapy**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***November 2001 (as adopted from UPMC Health Plan)***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Vytorin (Ezetimibe/Simvastatin).

Vytorin (Ezetimibe/Simvastatin) is indicated for the adjunctive therapy to diet to reduce elevated total cholesterol, low density lipoprotein (LDL) cholesterol, Apolipoprotein, triglycerides (TG), and non-high density lipoprotein (non-HDL) cholesterol, and to increase high density lipoprotein (HDL) cholesterol in patients with primary (heterozygous familial and non-familial) hyperlipidemia or mixed hyperlipidemia. It also is indicated to reduce elevated total cholesterol and low density lipoprotein cholesterol in patients with homozygous familial hypercholesterolemia, as an adjunct to other lipid-lowering treatments. No incremental benefit of ezetimibe/simvastatin (Vytorin) on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin (Zocor) has been established. Ezetimibe/Simvastatin (Vytorin) has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.

DEFINITIONS

N/A

POLICY

It is the policy of the Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy & Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug, Vytorin (Ezetimibe/Simvastatin), is subject to the prior authorization process.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed below:

- The criterion for automatic coverage of ezetimibe/simvastatin (Vytorin) is as follows:
  - Must have a documented pharmacy claim history for an HMG-CoA reductase inhibitor in the past 3 months

- For members without a documented claim history of an HMG-CoA reductase inhibitor, a medical necessity review is completed, and the following criterion must be met:
  - Must have chart documentation which shows the member has failed an HMG-CoA reductase inhibitor

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	Up to duration of member's membership with plan
Reauthorization	N/A

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Vytorin [package insert]. Whitehouse Station, NJ/ Kenilworth, NJ: Merck/ Schering- Plough Pharmaceuticals; February 2013.
2. Grundy SM, Cleeman JI, Bairey CN, et al. Implications of Recent Clinical Trials for the National Cholesterol Education Program Adult Treatment Panel III Guidelines. *Circulation.* 2004; 110:227-239.
3. Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults. Executive Summary of the Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). *JAMA.* 2001;285:2486-2497.

RECORD RETENTION

Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17, 02/18*
Removal of Liptruzet	*06/16*