

## Pharmacy Medical Necessity Guidelines: Ezetimibe/Simvastatin

Effective: February 9, 2021

|  |    |   |      |
|--|----|---|------|
| Prior Authorization Required   | √  | Type of Review – Care Management                  |      |
| Not Covered  |    | Type of Review – Clinical Review                  | √    |
| Pharmacy (RX) or Medical (MED) Benefit   | RX | Department to Review                              | RXUM |
| <p>These pharmacy medical necessity guidelines apply to the following:</p> <p><b>Commercial Products</b></p> <input type="checkbox"/> Tufts Health Plan Commercial products – large group plans<br><input type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans<br><input type="checkbox"/> Tufts Health Freedom Plan products – large group plans<br><input type="checkbox"/> Tufts Health Freedom Plan products – small group plans<br><ul style="list-style-type: none"> <li>CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</li> </ul> <p><b>Tufts Health Public Plans Products</b></p> <input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)<br><input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans<br><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan |    | <p><b>Fax Numbers:</b><br/>RXUM: 617.673.0988</p> |      |

**Note:** This guideline does not apply to Medicare Members (includes dual eligible Members).

### OVERVIEW

#### FDA-APPROVED INDICATIONS

Ezetimibe/simvastatin is indicated as adjunctive therapy to diet to:

- Reduce elevated total-C, LDL-C, 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.
- Reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid lowering treatments.

### COVERAGE GUIDELINES

The plan may authorize coverage of ezetimibe/simvastatin for Members when the following criterion is met and limitations do not apply:

- The Member has tried and failed or the provider indicates clinical inappropriateness of concomitant therapy with a generic statin and ezetimibe

### LIMITATIONS

- Simvastatin/ezetimibe should not be taken concurrently with other statins.
- The quantity is limited to one tablet per day.
- Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria.

### CODES

None

### REFERENCES

- Zetia [package insert]. White Station, NJ: Merck Sharp & Dohme Corp.; August 2013.
- Vytorin [package insert]. White Station, NJ: Merck Sharp & Dohme Corp.; September 2020.
- 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines. Circulation 2013, accessed at [circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.citation](http://circ.ahajournals.org/content/early/2013/11/11/01.cir.0000437738.63853.7a.citation)
- 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) Executive Summary. National Cholesterol Education Program National Heart, Lung, and Blood Institute. National Institutes of Health. May 2001; NIH Publication No. 01-3670.
- Grundy SM, Stone NJ, Bailey AL, et al. 2018  
AHA/ACC/AACVPR/AAPA/ABC/ACM/ADA/AGS/APhA/ASPC/NLA/PCNA. Guideline on the management of blood cholesterol. Doi: <https://doi.org/10.1016/j.jacc.2018.11.003>.

6. Arnett DK, Blumenthal RS, Abert MA, et al. 2019 ACC/AHA Guideline on the primary prevention of cardiovascular disease. *Circulation*. 2019;240:e596-e646.

#### **APPROVAL HISTORY**

April 12, 2007: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. July 19, 2012: No Changes
2. July 8, 2014: No Changes
3. July 14, 2015: Approval duration modified to 2 years.
4. September 16, 2015: Approval duration modified to life of plan.
5. January 1, 2016: Administrative change to rebranded template.
6. September 13, 2016: No changes.
7. April 11, 2017: Administrative update. Effective 6/1/2017, Medical Necessity Guideline applies to Tufts Health RITogether. Updated criteria to require that a member have an inadequate response to at least two generic statins.
8. September 12, 2017: Administrative update. Reflected the generic availability of Vytorin (simvastatin/ezetimibe). Removed from the limitations section "Quantities that exceed the quantity limit will be reviewed according to the Drugs with Quantity Limitations criteria." Added to the limitations section "Requests for brand-name products, which have AB-rated generics, will be reviewed according to Brand Name criteria."
9. November 13, 2018: Administrative changes made to template.
10. March 12, 2019: Effective 4/1/2019, updated name of MNG from "Lipid Absorption Inhibitors" to "Ezetimibe/Simvastatin". Removed criteria for ezetimibe, as it is now covered. Effective 7/1/2019, updated criteria for ezetimibe/simvastatin to require trial and failure with a generic statin in combination with ezetimibe.
11. February 11, 2020: No changes.
12. February 9, 2021: No changes.

#### **BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION**

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member's benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.

[Provider Services](#)