HMG-Co-A Reductase Inhibitors & Ezetimibe Products
Effective June 19, 2019

Plan	☒ MassHealth ☐Commercial/Exchange	**Program Type**	☐ Prior Authorization ☐ Quantity Limit ☒ Step Therapy
Benefit	☒ Pharmacy Benefit ☐ Medical Benefit (NLX)		
Specialty Limitations	N/A		
Contact Information	**Specialty Medications**		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	Non-Specialty Medications		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	Medical Specialty Medications (NLX)		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
Exceptions	N/A		

Overview

Prescriptions that meet the initial step therapy requirements will adjudicate automatically at the point of sale. If the prescription does not meet the initial step therapy requirements, the prescription will deny with a message indicating that prior authorization (PA) is required. Refer to the criteria below and submit a PA request for the members who do not meet the initial step therapy requirements at the point of sale.

Initial Step-Therapy Requirements:
First-Line: Medications listed on first-line are covered without prior-authorization.
Second-Line: Second-line medications will pay if the member has filled at least two first-line medications or a second-line medication within the past 180 days.
Third-Line: Ezetimibe will pay if the member has filled rosuvastatin or ezetimibe within the past 180 days.

Coverage Guidelines

FIRST-LINE	SECOND-LINE	THIRD-LINE
lovastatin pravastatin simvastatin atorvastatin	rosuvastatin fluvastatin fluvastatin ER	ezetimibe

Dosing Reference of Comparative Statin Potencies Available in Appendix

If a member does not meet the initial step therapy requirements, then approval of a second-line medication will be granted if the member meets the following criteria:

Rosuvastatin

1. Patient has had a documented inadequate response, side effect, or allergy to simvastatin and atorvastatin

OR

1. Patient requires a reduction in LDL cholesterol of at least 45% from baseline **AND**
2. Patient has had a documented inadequate response, side effect, or allergy to atorvastatin

Fluvastatin and Fluvastatin ER

1. Patient has had a documented inadequate response, side effect, or allergy to two first-line agents

Ezetimibe

1. Patient has had a documented inadequate response, side effect, or allergy to simvastatin, atorvastatin and rosuvastatin

Limitations

1. Approvals will be granted for 36 months.

Appendix

Drug Interactions:

Simvastatin/Simvastatin- Ezetimibe co-administration with other drugs:

- For patients taking amiodarone, verapamil, or diltiazem: the dose of simvastatin alone or as part of ezetimibe/simvastatin should not exceed 10 mg/day.
- For patients taking amlodipine or ranolazine: the dose of simvastatin alone or as part of ezetimibe/simvastatin should not exceed 20 mg/day.

Simvastatin/ Simvastatin- Ezetimibe contraindications:

- Concomitant administration of strong CYP3A4 inhibitors (e.g., itraconazole, ketoconazole, posaconazole, HIV protease inhibitors, erythromycin, clarithromycin, telithromycin & nefazodone).
- Concomitant administration of gemfibrozil, cyclosporine, or danazol.

Lipid-lowering potency of Statins

generic name	Potency (Average decrease in LDL)
atorvastatin	10 mg: 35-39%
	20 mg: 43%
	40 mg: 50%
	80 mg: 60%
fluvastatin ER	20 mg: 22%
	40 mg: 25%
	80 mg: 35%
lovastatin	10 mg: 21%
	20 mg: 24-27%
	40 mg: 30-31%
	80 mg:40-42% (as 40mg BID)
pravastatin	10 mg: 22%
	20 mg: 32%
	40 mg: 34%

	80 mg: 37%
rosuvastatin	5 mg: 45%
	10 mg: 46-52%
	20 mg: 47-55%
	40 mg: 55-63%
simvastatin	5 mg: 26%
	10 mg: 30%
	20 mg: 38%
	40 mg: 29-41%
	80 mg: 36-47% (FDA Recommends limited use)

Courtesy of Pharmacist's Letter/Prescriber's Letter. June 2010:(6); No. 260611.

References

1. Altoprev (lovastatin) [prescribing information]. Zug, Switzerland: Covis Pharma; April 2018.
2. Lescol/Lescol XL [package insert]. East Hanover, NJ: Novartis; August 2017.
3. Lipitor® [package insert]. New York, NY; Pfizer, Inc. 2019 Apr
4. Pravachol (pravastatin) [prescribing information]. Princeton, NJ: Bristol-Myers Squibb; March 2017.
5. Crestor (rosuvastatin) [prescribing information]. Wilmington, DE: AstraZeneca; November 2018.
6. Zetia (ezetimibe) [prescribing information]. Whitehouse Station, NJ: Merck/Schering-Plough; August 2013.
7. Zocor (simvastatin) [prescribing information]. Whitehouse Station, NJ: Merck & Co Inc; March 2019.
8. Jellinger PS, Handelsman Y, Rosenblit PD, et al. American Association of Clinical Endocrinologists and American College of Endocrinology guidelines for management of dyslipidemia and prevention of cardiovascular disease. Endocr Pract. 2017;23(suppl 2):1-87.[PubMed 28437620

Review History

09/29/03 – Reviewed
12/19/05 – Updated
11/27/06 – Updated
11/26/07 – Updated
07/16/07 – Pravastatin 80mg
11/24/08 – Drug look-backs and Vytorin
11/23/09 – Updated
11/22/10 – Reviewed
07/18/11 – FDA warning simvastatin 80mg
11/28/11 – Updated
06/15/12 – Lescol generic
11/26/12 – Reviewed
07/01/13 – Crestor to 3rd-line
10/01/13 – Crestor look-back for self-added
11/25/13 – Updated
11/24/14 – Updated
09/21/15 – Reviewed
09/19/16 – Reviewed
09/18/17 – Reviewed

09/24/18 – Updated
06/19/19 – Fluvastatin to 2nd line, remove Altoprev, Livalo and ezetimibe/simvastatin; retire for ComExch

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