



PHARMACY MEDICAL POLICY

Policy #: 013

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Title

Antihyperlipidemics

Advicor[®] (lovastatin/niacin ER); **Altoprev**[®] (lovastatin ER); **Caduet**[®] (amlodipine/atorvastatin); **Crestor**[®] (rosuvastatin); **Lescol/XL**[®] (fluvastatin); **Lipitor**[®] (atorvastatin); lovastatin; **Mevacor**[®] (lovastatin); **Pravachol**[®] (pravastatin); pravastatin; simvastatin; **Simcor**[®] (simvastatin/niacin); **Vytorin**[™] (ezetimibe/simvastatin); **Zetia**[™] (ezetimibe); **Zocor**[®] (simvastatin)

Prescription Drug Step Therapy

Note: Prescription drugs are covered to the extent that these types of services are generally covered by each member’s benefit design. The Formulary Exception/Prior Authorization form is included as part of this document for the physicians to submit for patients who do not meet the step therapy criteria at the point of sale. Physicians may also call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients at (800)366-7778.

Quality Care Dosing guidelines may apply to the following medications and can be found in Medical Policy #621.

Please refer to the chart below for the formulary status of the medications affected by this policy.

Standard Formulary	
Drug	Formulary Status
STEP 1	
<ul style="list-style-type: none"> • Lipitor[®] 80mg • Lovastatin • Pravastatin • Simvastatin 	Covered
STEP 2	
<ul style="list-style-type: none"> • Advicor[®] • Crestor[®] • Vytorin[®] • Zetia[®] 	Prior use of Step 1 required
STEP 3	
<ul style="list-style-type: none"> • Lipitor[®] * (10, 20, 40mg) 	Prior use of Step 1 AND Step 2 required
STEP 4	
<ul style="list-style-type: none"> • Altoprev[®]* • Caduet[®]* • Lescol[®]* • Lescol XL[®]* • Mevacor[®]* • Pravachol[®] 	Prior use of Step1, Step 2 AND Step 3 required

Standard Formulary	
Drug	Formulary Status
• Simcor ^{®*}	
• Zocor [®]	

Blue Value Formulary	
Drug	Formulary Status
STEP 1	
• Lipitor [®] 80mg	Covered
• lovastatin	
• pravastatin	
• Simvastatin	
STEP 2	
• Advicor [®]	Prior use of Step 1 required
• Crestor [®]	
• Vytorin [®]	
• Zetia [®]	
STEP 3	
• Lipitor [®] (10, 20, 40mg)	Prior use of Step 1 AND Step 2 required
STEP 4	
• Altoprev ^{®*}	Prior use of Step1, Step 2 AND Step 3 required
• Caduet ^{®*}	
• Lescol ^{®*}	
• Lescol XL ^{®*}	
• Mevacor ^{®*}	
• Pravachol ^{®*}	
• Simcor ^{®*}	
• Zocor ^{®*}	

Medicare HMO, PPO Blue & Medicare PFFS Formulary	
Drug	Formulary Status
STEP 1	
• Lipitor [®] 80mg	Covered
• Lovastatin	
• Pravastatin	
• Simvastatin	
STEP 2	
• Crestor [®]	Prior use of Step 1 required
• Vytorin [®]	
• Zetia [®]	
STEP 3	
• Lipitor [®] (10, 20, 40mg)	Prior use of Step 1 AND Step 2 required
STEP 4	
• Advicor ^{®*}	Prior use of Step1, Step 2 AND
• Altoprev ^{®*}	
• Caduet ^{®*}	
• Lescol ^{®*}	

• Lescol XL ^{®*}	Step 3 required
• Mevacor ^{®*}	
• Pravachol ^{®*}	
• Simcor ^{®*}	
• Zocor ^{®*}	

*Non formulary medications are covered when a formulary exception request is submitted to BCBSMA Pharmacy Operations and step criteria below are met.

When services are covered

We cover the following antihyperlipidemics listed in the chart above for new starts* in the following stepped approach³:

*New start is defined as no previous paid claim for the requested medication within the past 180 days.

Step 1¹: Formulary step 1 medications will be covered without prior authorization.

Note:

- Crestor (rosuvastatin) will pay at the point of sale without step therapy requirements when the prescription is written by a board certified/board eligible cardiologist or board certified/board eligible endocrinologist credentialed with Blue Cross Blue Shield of Massachusetts.
- Lipitor 80mg is covered as a Step 1 drug for members who have had an Acute Coronary Syndrome.

Step 2¹: Formulary step 2 medications will be covered when **one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use the patient of a Step 1 drug within the previous 180 days.

OR

- There must be evidence of a BCBSMA paid claim by the patient of a Step 2 drug within the previous 180 days.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

Step 3¹: Formulary step 3 medications will be covered when **one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a Step 1 drug within the previous 180 days.

AND

- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a Step 2 drug within the previous 180 days.

OR

- There must be evidence of a BCBSMA paid claim by the patient of a Step 3 drug within the previous 180 days.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

Step 4^{1,2}: Multi Source brands and Non-Formulary Step 4 medications are covered when a formulary exception request is submitted and approved by BCBSMA Pharmacy Operations and when **one** of the following criteria is met:

- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a Step 1 drug within the previous 180 days.

AND

- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a Step 2 drug within the previous 180 days.

AND

- There must be evidence of a BCBSMA paid claim or physician documented use by the patient of a Step 3 drug within the previous 180 days.

OR

- There must be evidence of a BCBSMA paid claim by the patient of a Step 4 drug within the previous 180 days.

**Requests based exclusively on the use of samples will not meet coverage criteria for exception. Additional clinical information demonstrating medical necessity of the desired medication must be submitted by the requesting prescriber for review.

When services are not covered

We do not cover drugs listed in the above chart when the above step therapy criteria are not met.

Individual consideration

All our medical policies are written for the majority of people with a given condition. For many of our medical policies, each individual's unique clinical circumstances may be considered. Physicians may send relevant clinical information for individual patients who do not meet the on line step therapy criteria for coverage consideration to:

Clinical Pharmacy Department
25 Technology Place
Hingham, MA 02043
Fax: 1-800-583-6289

For Medicare Advantage Requests:
Fax: 1-866-463-7700

Managed care, PPO and Indemnity guidelines

- Step Therapy **is** required when these drugs are processed through our point of sale electronic pharmacy benefit.
- Physicians may call BCBSMA Pharmacy Operations department to request a review for prior authorization for patients:
Pharmacy Operations: (800)366-7778
- Physicians may also fax or mail the attached form to the address above. The Formulary Exception/Prior Authorization form is included as part of this document for physicians to submit for patients who do not meet the step therapy criteria for antihyperlipidemics at the point of sale.

Coding information

- Physician billing is not applicable as these medications are processed as a pharmacy benefit.

Definitions

atherosclerosis: process in which deposits of fatty substances, cholesterol, cellular waste products, calcium and other substances build up in the inner lining of an artery

cholesterol: regulates membrane fluidity, and functions as a precursor molecule in various metabolic pathways and as a constituent of LDL may cause arteriosclerosis

LDL: low density lipoprotein, correlated with increased risk of atherosclerosis

lipid: general term for a fat

HDL: high density lipoprotein, correlated with reduced risk of atherosclerosis

HMG-CoA: 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase. This enzyme catalyzes the conversion of HMG-CoA to mevalonate, an early and rate-limiting step in cholesterol biosynthesis.

Policy update history

Medical policy issued March 2003; effective March 2003. Updated to include formulary information for Blue Value Rx and Medicare HMO and Medicare PPO Blue. Updated 3/06 to include the HMG-COA reductase inhibitors and revised look back period for paid claims from 130 days to 180 days. Reviewed 2/06 MPG- Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. Updated 4/06 to include a new PA form, sample language and to have Lipitor 80mg as Step 1 drug for ACS and Caduet as Step 4 drug. Reviewed 4/06 MPG- cardiology, no changes in coverage were made. Updated 6/06 to include simvastatin as a Step 1 drug. Updated 8/06 to move Zocor and Pravachol 10, 20 and 40 mg from Step 1 to Step 3. Reviewed 2/07 MPG- Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. Reviewed 4/07 MPG Cardiology, no changes in coverage were made. Updated 7/07 to move Zocor and Pravachol brand names to Step 2 except Medicare HMO & PPO formulary and revision of request form. Reviewed 2/08 MPG- Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. Reviewed 4/08 MPG- Cardiology, no changes in coverage were made. Updated 9/08 to include Simcor to medical policy. Updated 1/09 to remove non-formulary designation of Step 4. Reviewed 2/09 MPG – Psychiatry, Ophthalmology and Endocrinology, no changes in coverage were made. Reviewed 4/09 MPG – Cardiology, no changes in coverage were made.

Scientific background, Rationale and References

¹ BCBSMA maintains a list of non-covered drugs for a variety of therapeutic drug classes, including the HMG-CoA reductase inhibitors class, for most non-senior products.

² Physicians can request coverage of a non-covered drug by submitting a Formulary Exception request.

³ Approved formulary exceptions will adjudicate with a third tier copay for members with a three-tier pharmacy benefit.

⁴ Based on manufacturers dosing recommendations.

⁵ Based on the recommendation of the BCBSMA Pharmacy and Therapeutics Committee, 02/2003

References:

- Callister T. Q., Raggi P., Cooil B., Lippolis N. J., Russo D. J. Effect of HMG-CoA Reductase Inhibitors on Coronary Artery Disease as Assessed by Electron-Beam Computed Tomography N Engl J Med 1998; 339:1972-1978, Dec 31, 1998.
- Charles R. Harper, MD; Terry A. Jacobson, MD New Perspectives on the Management of Low Levels of High-Density Lipoprotein Cholesterol Archives of Internal Medicine / volume:159 (page: 1049)
- Thomas A. Pearson, MD, PhD, MPH; Irene Laurora, PharmD; Henry Chu, MS; Stephanie Kafonek, MD The Lipid Treatment Assessment Project (L-TAP): A Multicenter Survey to Evaluate the Percentages of Dyslipidemic Patients Receiving Lipid-Lowering Therapy and Achieving Low-Density Lipoprotein Cholesterol Goals Archives of Internal Medicine / volume:160 (page: 459)

This document is designed for informational purposes only and is not an authorization, or an explanation of benefits, or a contract. Receipt of benefits is subject to satisfaction of all terms and conditions of the coverage. Medical technology is constantly changing, and we reserve the right to review and update our policies periodically.

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Request for Outpatient Retail Pharmacy Prior Authorization for Antihyperlipidemics (#013)

**Fax to: Clinical Pharmacy Program (800) 583-6289 or for
Medicare Advantage HMO Blue /PPO Blue: (866)463-7700**

We plan to respond to your request within two business days of our receipt. To ensure that we can confirm your request (required by NCQA), please be sure to include your fax number.

We cannot process requests unless they contain all of the information requested below:	
Patient Information (REQUIRED)	
Name	
BCBSMA ID Number	
Is the patient a BCBSMA employee? If yes, please fax request to: (617) 246-4013	Yes No
Date of Birth	_ _ / _ _ / _ _ _ _
Patient's Diagnosis or ICD-9-CM code	
Physician Information (REQUIRED)	
Name	
Medical Specialty	
BCBSMA Provider number/NPI number	
Telephone Number	
Fax Number	
Contact Name (if different from physician)	
Outpatient Retail Pharmacy Prior Authorization Request	
Step 1 medications:	Lipitor [®] (80mg) lovastatin pravastatin simvastatin
Step 2 medications:	Advicor [®] Crestor [®] Vytorin [®] Zetia [®]
Step 3 medications:	Lipitor [®] (10,20,40mg)
Step 4 medications:	Altoprev [®] Caduet [®] Lescol/XL [®] Mevacor [®] Pravachol [®] Simcor [®] Zocor [®]
Dose: _____	Sig: _____ Qty: _____ *Please see lower box for QCD overrides
Clinical Information for Step 2, Step 3 & Step 4 medications :	
Previous treatment failure (excluding samples) within the previous 180 days (please check all that apply):	
Advicor [®]	Lipitor [®] (10,20,40mg) pravastatin Zocor [®]
Altoprev [®]	Lipitor [®] (80mg) Simcor [®]
Caduet [®]	lovastatin simvastatin
Crestor [®]	Mevacor [®] Vytorin [®]
Lescol/XL [®]	Pravachol [®] Zetia [®]
other clinical reason (please specify): _____	
Quality Care Dosing Override Request: Quantity Requested: _____ Clinical reason for override of QCD limit: _____	
MD Signature:	Date: