



## Lipid Management Step Therapy Criteria with Medical Diagnoses Option\*

\* Medical diagnoses are required for implementation of this option.

Program may be implemented with the following options:

Option One – 1-step edit, with generic HMG before brand HMG or HMG combination, or

Option Two – 2-step edit, with generic HMG before preferred brand HMG or combination, AND both generic HMG and preferred brand HMG or combination before any nonpreferred brand HMG or combination

**For Blue Cross and Blue Shield of Illinois, Option 1 (1-step program) will apply.**

Brand	Generic	Dosage Form
Advicor <sup>®</sup>	niacin extended-release/lovastatin	extended/immediate release tablet
Altoprev <sup>®</sup>	lovastatin	extended-release oral tablet
Mevacor <sup>®</sup>	lovastatin <sup>a</sup>	immediate-release oral tablet
Crestor <sup>®</sup>	rosuvastatin	immediate-release oral tablet
Lescol <sup>®</sup>	fluvastatin	immediate-release oral capsule
Lescol <sup>®</sup> XL	fluvastatin	extended-release oral tablet
Lipitor <sup>®</sup>	atorvastatin	immediate-release oral tablet
Livalo <sup>®</sup>	pitavastatin	immediate-release oral tablet
Pravachol <sup>®</sup>	pravastatin <sup>a</sup>	immediate-release oral tablet
Simcor <sup>®</sup>	niacin extended-release/ simvastatin	extended release oral tablet
Vytorin <sup>®</sup>	ezetimibe/simvastatin	immediate-release oral tablet
Zocor <sup>®</sup>	simvastatin <sup>a</sup>	immediate-release oral tablet

a - currently available as a generic

## FDA APPROVED INDICATIONS

**Table 1. FDA-Approved Indications and Clinical Trials Data<sup>1-20,28</sup>**

FDA Approved Indication (indicated by ✓)	Atorva	Fluva	Lova	Pitava	Prava	Simva	Rosuva	Simva/ ezetimibe	Niacin ER/ simva	Niacin ER/ lova
Primary hypercholesterolemia and mixed dyslipidemia (IIa, IIb) ↓ Total-C, ↓ LDL-C, ↓ Apo B, ↓ TG, ↑ HDL-C	✓ <sup>a</sup>	✓	✓ <sup>b</sup>	✓	✓	✓	✓	✓	✓	✓
Hypertriglyceridemia (IV)	✓	Data	Data		✓	✓	✓		✓	
Primary dysbetalipoproteinemia (III)	✓		Data		✓	✓				
Familial homozygous hyperlipidemia	✓		Data		Data	✓	✓	✓		
Familial heterozygous hyperlipidemia in children 8 years and older	✓ <sup>c</sup>	✓ <sup>c</sup>	✓ <sup>c</sup>		✓ <sup>d</sup>	✓ <sup>c</sup>				
<b>Primary Prevention of Heart Disease</b>	Yes	No	Yes		Yes	Yes	No	No	No	No
↓ risk of myocardial infarction	✓		✓		✓	Data				
↓ risk of undergoing a revascularization procedure	✓		✓		✓	Data				
↓ risk of cardiovascular mortality with no increase in death from non-cardiovascular causes			Data		✓	Data				
↓ risk of stroke	✓									
↓ risk of unstable angina	✓		✓							
<b>Secondary Prevention of Cardiovascular Events</b>	Yes	Yes	Yes		Yes	Yes	No	No	No	No
↓ risk of total mortality by decreasing coronary death	✓				✓	✓				
↓ risk of myocardial infarction	✓	Post PCI	Post CABG		✓	✓				
↓ risk of undergoing a revascularization procedure	✓	✓	Post CABG		✓	✓				
↓ risk of stroke and TIA	✓				✓	✓				
Slow progression of coronary atherosclerosis	Data	✓	✓		✓	Data	✓			
↓ risk of angina	✓									
↓ risk of hospitalization for HF	✓									

a - indicates has FDA approved indication

b - not indicated to ↓ Apo B, ↓ TG, ↑ HDL; produces changes similar to others

c - adolescents ages 10 to 16/17 years

d - children and adolescents 8 years and older

Data indicates that there are large studies demonstrating efficacy.

Post CABG and Post PCI indicate efficacy data exist but for a select population (i.e., post CABG or post PCI)

CABG = coronary artery bypass graft, PCI = percutaneous coronary intervention, TIA = transient ischemic attack

### CLINICAL RATIONALE FOR STEP THERAPY

The lipid management step therapy program encourages the use of cost-effective generic HMG Co-A Reductase inhibitors (HMGs) prior to the use of brand HMG agents for the management of high blood cholesterol. The program has been developed with the opportunity to implement one of two options; 1) a one-step edit that requires therapy with a generic HMG agent before any brand including the combination agents Advicor and Vytorin or 2) a two-step edit that requires use of a generic HMG agent before use of a preferred brand or combination HMG agent and therapy with both a generic and a preferred brand HMG agent when a non-preferred brand is requested. The medical diagnosis option can be implemented to accommodate the use of any HMG agent in those at highest risk for a major coronary event.

There are currently three HMG agents available as generics – lovastatin, pravastatin and simvastatin. For each of the diagnoses approved by the FDA for HMGs (primary hypercholesterolemia and mixed dyslipidemia, hypertriglyceridemia, dysbetalipoproteinemia, familial homozygous hyperlipidemia, and familial heterozygous hyperlipidemia in children) there is a generic with approved labeling for treatment of the diagnosis.<sup>1-9</sup> There is also a generic with approved labeling for the primary prevention of coronary of coronary events in patients without existing coronary heart disease and secondary prevention of cardiovascular events in patients with existing coronary heart disease (see Table 1).<sup>1-20</sup>

All of the HMG agents, when administered in approximately equivalent doses (see Table 2), can reduce LDL cholesterol up to 40 percent.<sup>21</sup> Reductions in LDL cholesterol of 40 percent to 49 percent can be

achieved with atorvastatin, rosuvastatin, lovastatin, and simvastatin.<sup>21</sup> Reductions in LDL cholesterol greater than 49 percent may be accomplished with atorvastatin doses of 40 mg daily or greater or rosuvastatin doses of 20 mg daily or greater.<sup>21</sup>

**Table 2. Equivalent Doses of Statins for LDL Cholesterol Lowering<sup>a 21</sup>**

atorvastatin	fluvastatin	lovastatin	pravastatin	rosuvastatin	simvastatin
--	40 mg	20 mg	20 mg	--	10 mg
10 mg	80 mg	40 or 80 mg	40 mg	--	20 mg
20 mg	--	80 mg	80 mg	5 or 10 mg	40 mg
40 mg	--	--	--	--	80 mg
80 mg	--	--	--	20 mg	--
--	--	--	--	40 mg	--

a - estimates for equipotent doses based on results from head-to-head trials

**Table 3. Percent Reduction in LDL Cholesterol with Statins<sup>22</sup>**

Daily Dose	Number of clinical trials <sup>a</sup>	LDL mean % lowering from head-to-head clinical trials only	LDL mean % lowering from manufacturer prescribing information (and ATP-III <sup>23</sup> if available)
<b>Atorvastatin</b>			
10mg	22	28.9% to 40.2%	39% (37%)
20mg	8	38.4% to 46.1%	43%
40mg	5	45.1% to 51.3%	50%
80mg	6	46.3% to 54%	60% <sup>b</sup> (57%)
<b>Fluvastatin</b>			
20mg	5	17% to 21.8%	22% (18%) <sup>f</sup>
40mg	6	22% to 26%	25% <sup>f</sup>
80mg	2	29.6% to 30.6% <sup>d</sup>	36% (31%) <sup>ef</sup>
80mg XL	0	-- <sup>c</sup>	35% <sup>f</sup>
<b>Lovastatin</b>			
10 mg	2	21.6% to 24%	21%
20mg	8	21% to 29%	27% (24%)
40mg	5	27.9% to 33%	31%
80mg	2	39% to 48%	42% (40%) <sup>g</sup>
<b>Pitavastatin<sup>h</sup></b>			
1mg	---	---	31-32%
2mg	---	---	36-39%
4mg	---	---	41-45%
<b>Pravastatin</b>			
10 mg	9	18% to 24.5%	22%
20mg	11	23% to 29%	32% (24%)
40mg	8	25.2% to 34%	34%
80mg	0	-- <sup>c</sup>	37% (34%)
<b>Rosuvastatin</b>			
5mg	6	39.1% to 46%	45%
10mg	9	37.1% to 50.6%	52%
20 mg	3	45.7% to 52.4%	55%
40mg	3	53.6% to 58.8%	63%
<b>Simvastatin</b>			
10mg	17	26% to 33.1%	30%
20mg	17	18.5% to 40%	38% (35%)
40mg	7	34.3% to 43%	41%
80mg	5	43% to 48.8%	47% (46%)

a - Randomized controlled trials that included at least two statins. % LDL-C reduction in clinical trials included in table only if data provided for a specific dosage and not a mean dosage

b - This is based on results of 23 patients. Clinical trial data at atorvastatin 80mg included more than 1750 patients.

c - Newly-approved dose or dosage form with no head-to-head clinical trial data against another statin.

d - Given as fluvastatin 80mg qd or 40mg bid (does not include XL product)

e - Given as fluvastatin 40mg bid

f - Median percent change

g - Given as lovastatin 40mg bid

h – Pitavastatin clinical trial data not included in reference 22; information from prescribing information only

HMG combination products with two lipid-lowering agents will be included in this step therapy program – Advicor, Simcor, and Vytorin. Caduet, a combination of amlodipine and atorvastatin, is not included in the criteria because it is not indicated exclusively for the treatment of hypercholesterolemia. Caduet is used in patients who require both lipid management and treatment of hypertension or angina.

There are insufficient head-to-head trials to compare equivalent doses of the combination agents, Advicor, Simcor, or Vytorin. Product labeling for Advicor, Simcor, and Vytorin indicates improved lipid-altering effects with the combination agent compared to each component.<sup>1,8,9</sup> There are no outcomes studies for Advicor, Simcor, or Vytorin. Outcomes (reduction in morbidity and mortality) from the Scandinavian Simvastatin Survival Study and the Heart Protection Study are applicable to simvastatin only, not the combinations of ezetimibe and simvastatin or niacin and simvastatin. Current prescribing information for Advicor states that the effect of combined therapy with niacin and lovastatin on cardiovascular morbidity and mortality has not been determined.<sup>1</sup> The HATS trial<sup>24</sup> (2001) did find that sustained release niacin (Slo-Niacin) in combination with simvastatin decreased rates of atherosclerotic progression and CHD events.<sup>24</sup> Current prescribing information for Simcor states that no incremental benefit of Simcor on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin monotherapy and niacin monotherapy has been established.<sup>8</sup>

The ENHANCE (Effect of Combination Ezetimibe and High-Dose Simvastatin vs. Simvastatin Alone on the Atherosclerotic Process in Patients with Heterozygous Familial Hypercholesterolemia) trial results were released by the manufacturer on January 14, 2008. The study involved 720 patients with heterozygous familial hypercholesterolemia. Patients were randomized to 80 mg of simvastatin daily with either placebo or 10 mg of ezetimibe per day. The results of the trial showed no significant difference in the primary endpoint (change in the mean carotid intima-media thickness or IMT) between patients treated with ezetimibe and simvastatin versus patients treated with simvastatin alone over a two-year period.<sup>25</sup>

According to the American College of Cardiology (ACC), this study deserves serious thought and follow-up. The overall incidence rates of cardiac events were nearly identical between both treatment groups, and both medicines were generally well tolerated. Further research will be needed in this area to provide conclusive evidence about which lipid lowering strategy is preferred (statin alone vs. statin plus ezetimibe). The ACC also notes that this trial is an imaging study and not a clinical-outcome study. Conclusions should not be made until the three large clinical-outcome trials are presented within the next two to three years. The ACC recommends that ezetimibe remains a reasonable option for patients who are currently on a high dose statin but have not reached their LDL cholesterol goal. The ACC also notes that ezetimibe is a reasonable option for patients who cannot tolerate statins or can only tolerate a low dose statin.<sup>26</sup>

### ***Medical Diagnoses Criteria***

The intent of the identification of patients with certain medical diagnoses is to allow coverage of brand HMGs in members who are at highest risk of a major coronary event.<sup>23,27</sup> The medical diagnoses listed below include myocardial infarction, coronary atherosclerosis disease (CAD), stroke, congestive heart failure, BOTH hypertension AND diabetes, or a surgical procedure for a coronary stent placement, percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG), or intracoronary thrombolysis infusion. They will be used to identify patients for pre-approval of brand HMGs through the implementation process. The utilization management step therapy program for brand HMGs will not be required for them. Medical claims data will be used to identify plan members with the ICD-9 codes listed below:

EVENT	ICD-9CM Code*	Surgical Code
Myocardial infarction	410/410.X/410.XX	----
Coronary atherosclerosis disease	411/411.X/411.XX – 414/414.X/414.XX	----
Stroke	433/433.X/433.XX – 438/438.X/438.XX	----
Heart Failure (including rheumatic)	398.91, 428/428.X/428.XX	----
PTCA, CABG, coronary stent placement, intracoronary thrombolysis infusion	V4581, V4582	36.0X, 36.1X, 36.2
Hypertension	401.0, 401.1, 401.9, 402/402.X/420.XX – 405/405.X/405.XX, 437.2	----
AND Diabetes Mellitus	250/250.X/250.XX	

\*The Medical Diagnoses Criteria will approve ICD-9 codes or surgical codes of three or more digits as applicable to ensure that members who have been assigned incomplete codes will be included.

These patients would be exempt from the prior authorization process for prescriptions for brand HMGs.

### **Step Therapy Electronic Edit**

The overall process for step therapy requires that another drug or drugs be tried for a specific quantity of drug in the previous time period before the claim drug. If the patient has met any of the requirements outlined below, the requested step therapy medication will be paid under the patient's current prescription benefit. If the patient does not meet the step therapy criteria, then the system will reject with the message indicating that prior authorization is necessary or that higher co-pay(s) will be applicable. The PA criteria for approval would then be applied to requests submitted by the patients' practitioner for evaluation.

#### **Option 1. Generic HMG before Brand HMG**

The implementation of this option encourages the use of cost-effective generic HMG agents prior to use of brand agents for the management of high blood cholesterol. The program approves for a brand HMG (including the combination agents Advicor, Simcor, and Vytorin) when there is history of generic use.

This step edit option has been designed as one edit that automatically pays for a brand HMG agent when a generic HMG is identified electronically in the claims history within a 90-day look back parameter. If a generic HMG is not found, a request for the brand is directed through a manual prior authorization (PA) process. This process allows use of the brand agent if there is previous use of a generic that does not appear in the claims history, or if the patient cannot use a generic due to allergy, intolerance, or contraindication. Brand agents may also be approved for use if the patient requires LDL lowering that cannot be achieved with available generic agents.

Claims for a brand HMG will also automatically pay if the patient's medication history contains evidence of the same brand HMG within 90 days prior to the new claim. The claims system is designed to identify any claim with a days supply that ends within the 90-day look-back timeframe. Approval of these agents if previous use is identified assures no disruption of therapy for those patients already stabilized on the medication. The 90-day search period was chosen to capture the most current therapy.

#### **Option 2. Generic HMG before Preferred Brand HMG before Non-preferred Brand HMG**

The implementation of this option encourages the use of cost-effective generic HMG agents prior to use of preferred brand agents for the management of high blood cholesterol. The edit allows for payment of nonpreferred brand agents when claims history indicates use of both a generic and a preferred brand HMG agent.

This step edit option has been designed as two edits; one for brand preferred HMG agents or combination HMG agents and one for nonpreferred brand HMGs. When the requested agent is a *preferred* brand or combination HMG agent, automatic payment occurs for the preferred brand when a generic HMG is identified electronically in the claims history within a 90-day look back parameter. If a generic HMG is not found, a request for the preferred brand or combination agent is directed through a manual PA process. This process allows use of the preferred brand or combination agent if there is

previous use of a generic that does not appear in the claims history, or if the patient cannot use a generic due to allergy, intolerance, or contraindication. Preferred brand agents may also be approved for use if the patient requires LDL lowering that cannot be achieved with available generic agents.

**NOTE: as of 7/1/09, preferred brand Crestor claims will also pay automatically if there is a medication history of Lipitor 40 mg, Lipitor 80 mg, Vytorin 10/20, Vytorin10/40, or Vytorin 10/80 within 90 days prior to the Crestor claim.**

If the requested HMG agent is a *nonpreferred* brand agent, the edit requires a 180-day prior claims history of both a generic HMG agent and a preferred brand agent. If both are found, the claim pays automatically. If both are not found, a request for the non-preferred agent is directed through a manual PA process. Use of the nonpreferred agent is approved if there is prior use of both generic HMG and a preferred brand but no electronic claims history or if there is an allergy, intolerance, or contraindication to both or if lipid reduction goals cannot be met with the available generic HMG agents or preferred brand HMG agents.

Claims for a brand HMG (preferred or nonpreferred) will also automatically pay if the patient's medication history contains evidence of the same brand HMG within 90 days prior to the new claim. The claims system is designed to identify any claim with a days supply that ends within the 90-day look-back timeframe. Approval of these agents if previous use is identified assures no disruption of therapy for those patients already stabilized on the medication. The 90-day search period was chosen to capture the most current therapy.

### ***Prior Authorization (PA) Criteria for Approval***

The intent of the *PA Criteria for Approval* is to ensure that patients who have been unable to tolerate the generic and/or preferred brand HMG agent(s), or have not had adequate response to one of these agents, have the option of treatment with another HMG. Approval will be given to patients who have a history of use and failure outside of the 90 and 180 day look-back period or outside of the current benefit plan. A preferred or nonpreferred brand HMG may be approved if the patient is unable to use a generic or preferred HMG agent because of allergy, intolerance, contraindication, or treatment failure.

Preferred or nonpreferred brand HMGs will also be approved indefinitely in patients who are classified as at high risk of a major coronary event, due to their high risk for significant disease morbidity. Indefinite approvals granted through the PA process may be re-evaluated at some future time if new information changes selection criteria or safety issues develop that place patients at higher risk from drug therapy.

## **INITIAL AUTOMATIC STEP THERAPY EDIT FUNCTIONALITY**

### **Option 1**

#### *Request for a brand HMG*

In order for a claim for a brand HMG to pay automatically, the patient must have evidence of a claim for a generic HMG agent (GPI 394000\*\*\*\*\*, multi-source code Y) in their claims history within 90 days prior to the brand HMG claim. The 90-day look-back parameter allows for identification of trial and failure of a generic prior to the new brand claim.

The brand HMG will also automatically pay if there is a medication history of an identical GPI to the requested brand HMG agent within 90 days prior to the claim. The 90-day look-back period is intended to identify recent claims and assure continuation of therapy. The claims system is designed to identify and count any generic HMG claim or brand HMG claim with a days supply that overlaps into the 90-day look-back period.

A claim for any brand HMG will also pay automatically if the patient is at high risk of a major coronary event based on documented medical diagnosis.

If the patient has met the requirements defined above, the requested brand HMG agent will be paid automatically at the applicable copayment under the patient's current prescription drug benefit. If the step therapy edit is not met, a Point of Sale message will be returned to the pharmacy stating the step is not met and prior authorization is required. The Prior Authorization (PA) Criteria for Approval would then be applied to requests submitted by the patient's practitioner for evaluation.

## Option 2

### 1) Request for preferred brand HMG

In order for a claim for a preferred brand HMG to pay automatically, the patient must have evidence of a claim for a generic HMG agent (GPI 394000\*\*\*\*\*, multi-source code Y) in their claims history within 90 days prior to the brand HMG claim. The 90-day look-back parameter allows for identification of trial and failure of a generic prior to the new preferred brand HMG claim.

**NOTE: as of 7/1/09, preferred brand Crestor claims will also pay automatically if there is a medication history of Lipitor 40 mg, Lipitor 80 mg, Vytorin 10/20, Vytorin10/40, or Vytorin 10/80 within 90 days prior to the Crestor claim.**

### 2) Request for nonpreferred brand HMG agent

In order for a claim for nonpreferred brand HMG agent to pay automatically, the patient must have medication history of a previous claim for a generic HMG agent (GPI 394000\*\*\*\*\*, multi-source code Y) and a claim for a preferred brand HMG agent [GPI is dependant upon plan-preferred agent(s)] within 180 days prior to the new claim for a nonpreferred HMG. The 180 day look-back parameter is used as an adequate time frame for trial and failure of two HMG agents.

A brand HMG (preferred or nonpreferred) will also automatically pay if there is a medication history of an identical GPI to the requested brand HMG agent within 90 days prior to the claim. The 90-day look-back period is intended to identify recent claims and assure continuation of therapy. The claims system is designed to identify and count any generic HMG claim or brand HMG claim with a days supply that overlaps into the 90-day look-back period.

A claim for any brand HMG will also pay automatically if the patient is at high risk of a major coronary event based on documented medical diagnosis.

If the patient has met the requirements defined above, the requested brand HMG agent will be paid automatically at the applicable copayment under the patient's current prescription drug benefit. If the step therapy edit is not met, a Point of Sale message will be returned to the pharmacy stating the step is not met and prior authorization is required. The Prior Authorization (PA) Criteria for Approval would then be applied to requests submitted by the patient's practitioner for evaluation.

## PRIOR AUTHORIZATION CRITERIA FOR APPROVAL

### Option 1 – 1-Step Program

#### Initial and Renewal Evaluation for *Brand HMG or Combination HMG agent (e.g., Advicor, Simcor, or Vytorin)*

1. Is the patient currently being treated with the requested brand HMG or combination HMG?  
If yes, approve for 12 months. If no, continue to 2.
2. Does the patient have a medical diagnosis that puts them at a high risk of major coronary event (defined as myocardial infarction, coronary atherosclerosis disease (CAD), stroke, congestive heart failure, BOTH hypertension AND diabetes, or a surgical procedure for a coronary stent placement, percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG), or intracoronary thrombolysis infusion)?  
If yes, approve indefinitely. If no, continue to 3.
3. Does the patient's medication history include use of a generic HMG agent (lovastatin, pravastatin, simvastatin)?  
If yes, approve indefinitely. If no, continue to 4
4. Does the patient have a contraindication, allergy, or intolerance, to the available generic agents?  
If yes, approve indefinitely. If no, continue to 5.

5. Does the patient require LDL lowering that cannot be achieved with the available generic agent(s)? (defined as greater than 40% LDL lowering, which Table 3 lists as achievable with simvastatin 40 mg once daily or lovastatin 40 mg twice daily)  
If yes, approve indefinitely. If no, deny.

## Option 2– 2-Step Program

### Initial and Renewal Evaluation for *Preferred Brand HMG or Combination HMG agent (e.g., Advicor, Simcor, or Vytorin)*

1. Is the patient currently being treated with the requested brand HMG or combination HMG?  
If yes, approve for 12 months. If no, continue to 2.
2. Does the patient have a medical diagnosis that puts them at a high risk of major coronary event (defined as myocardial infarction, coronary atherosclerosis disease (CAD), stroke, congestive heart failure, BOTH hypertension AND diabetes, or a surgical procedure for a coronary stent placement, percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG), or intracoronary thrombolysis infusion)?  
If yes, approve indefinitely. If no, continue to 3.
3. Does the patient's medication history include use of a generic HMG agent (lovastatin, pravastatin, simvastatin)?  
If yes, approve for 12 months. If no, continue to 4

**NOTE: as of 7/1/09, criteria for preferred brand Crestor will also be met if there is a medication history of Lipitor 40 mg, Lipitor 80 mg, Vytorin 10/20, Vytorin10/40, or Vytorin 10/80.**

4. Does the patient have a contraindication, allergy, or intolerance, to the available generic agents?  
If yes, approve for 12 months. If no, continue to 5.
5. Does the patient require LDL lowering that cannot be achieved with the available generic agent(s)? (defined as greater than 40% LDL lowering, which Table 3 lists as achievable with simvastatin 40 mg once daily or lovastatin 40 mg twice daily)  
If yes, approve for 12 months. If no, deny.

### Initial and Renewal Evaluation for *Nonpreferred Brand HMG*

1. Is the patient currently being treated with the requested brand HMG or combination HMG?  
If yes, approve for 12 months. If no, continue to 2.
2. Does the patient have a medical diagnosis that puts them at a high risk of major coronary event (defined as myocardial infarction, coronary atherosclerosis disease (CAD), stroke, congestive heart failure, BOTH hypertension AND diabetes, or a surgical procedure for a coronary stent placement, percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG), or intracoronary thrombolysis infusion)?  
If yes, approve indefinitely. If no, continue to 3.
3. Does the patient's medication history include use of a generic HMG agent (lovastatin, pravastatin, simvastatin)?  
If yes, continue to 6. If no, continue to 4

**NOTE: as of 7/1/09, criteria for preferred brand Crestor will also be met if there is a medication history of Lipitor 40 mg, Lipitor 80 mg, Vytorin 10/20, Vytorin10/40, or Vytorin 10/80.**

4. Does the patient have a contraindication, allergy, or intolerance, to the available generic agents?  
If yes, continue to 6. If no, continue to 5.
5. Does the patient require LDL lowering that cannot be achieved with the available generic agent(s)? (defined as greater than 40% LDL lowering, which Table 3 lists as achievable with simvastatin 40 mg once daily or lovastatin 40 mg twice daily)  
If yes, continue to 6. If no, deny.

6. Does the patient's medication history include use of a preferred brand?  
If yes, approve for 12 months. If no, continue to 7.
7. Does the patient have a contraindication, allergy, or intolerance, to the available preferred brand agents?  
If yes, approve for 12 months. If no, continue to 8
8. Does the patient require LDL lowering that cannot be achieved with the available preferred brand HMG(s) (defined as greater than 50% LDL lowering, which Table 3 lists as achievable with Crestor 10 mg or 20 mg)?  
If yes, approve for 12 months. If no, deny.

## SUMMARY

Step therapy electronic edits are designed to identify patients electronically by their medication history and automatically approve claims that would meet prior authorization criteria. The Lipid Management Step Therapy edit allows for automatic payment of claims for brands (one-step option) or preferred brands (two-step option) when the patient's medication history indicates prior use of generic lovastatin, pravastatin, or simvastatin, bypassing the manual PA process. Use of a nonpreferred brand requires prior use of a generic and preferred brand in a two-step option. The step therapy process allows for automatic payment of a brand HMG when a medical diagnosis placing the patient at high risk for a major coronary event is documented. The PA process provides a member-specific review process where practitioner provided patient-specific parameters are taken into consideration. The step therapy protocol for HMGs optimizes the utilization of cost-effective agents for the individual benefit plan.

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Original Prime Standard approved by External UM Committee 05/2006  
 Client Specific Review (option 1, with auto-grandfathering) approved by HCSC Corporate Clinical Committee 08/2006  
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