Title: Statin Therapy

- Prime Therapeutics will review Prior Authorization requests.

Prior Authorization Form:

Link to Drug List (Formulary):
http://www.bcbsks.com/CustomerService/PrescriptionDrugs/drug_list.shtml

Professional
Original Effective Date: January 1, 2010
Revision Date(s): May 20, 2011;
August 30, 2012; January 1, 2013;
July 1, 2013; January 1, 2014;
October 28, 2014; October 1, 2015;
September 1, 2016; May 15, 2017
Current Effective Date: May 15, 2017

Institutional
Original Effective Date: January 1, 2010
Revision Date(s): May 20, 2011;
August 30, 2012; January 1, 2013;
July 1, 2013; January 1, 2014;
October 28, 2014; October 1, 2015;
September 1, 2016; May 15, 2017
Current Effective Date: May 15, 2017

State and Federal mandates and health plan member contract language, including specific provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage. To verify a member’s benefits, contact Blue Cross and Blue Shield of Kansas Customer Service.

The BCBSKS Medical Policies contained herein are for informational purposes and apply only to members who have health insurance through BCBSKS or who are covered by a self-insured group plan administered by BCBSKS. Medical Policy for FEP members is subject to FEP medical policy which may differ from BCBSKS Medical Policy.

The medical policies do not constitute medical advice or medical care. Treating health care providers are independent contractors and are neither employees nor agents of Blue Cross and Blue Shield of Kansas and are solely responsible for diagnosis, treatment and medical advice.

If your patient is covered under a different Blue Cross and Blue Shield plan, please refer to the Medical Policies of that plan.
DESCRIPTION
The intent of the Statin Prior Authorization program is to encourage the use of cost-effective generic statins (HMG Co-A reductase inhibitors) prior to the use of brand statins for the management of high blood cholesterol. This 1-step program includes all brand statin or statin combination products as targets requiring use of a generic statin or statin combination prior to their use. The program will evaluate use of a brand statin or statin combination product through the prior authorization process when patients are unable to take a generic statin or statin combination due to documented intolerance, FDA labeled contraindication, or hypersensitivity. Requests for brand statins or statin combinations will be reviewed when patient-specific documentation has been provided.

Target Drugs (brands only)
- **Advicor**<sup>®</sup> (niacin extended release/lovastatin) <sup>b</sup>
- **Altoprev**<sup>®</sup> (lovastatin extended release)
- **Crestor**<sup>®</sup> (rosuvastatin) <sup>a</sup>
- **Lescol XL**<sup>®</sup> (fluvastatin extended release) <sup>a</sup>
- **Liptruzet**™ (ezetimibe/atorvastatin)
- **Livalo**<sup>®</sup> (pitavastatin)
- **Simcor**<sup>®</sup> (niacin extended release/simvastatin) <sup>a</sup>
- **Vytorin**<sup>®</sup> (ezetimibe/simvastatin)

<sup>a</sup> - currently available as a generic; included as a prerequisite in step therapy program
<sup>b</sup> - generic anticipated; will be included as a prerequisite in step therapy program when available

FDA Approved Indications and Dosage<sup>1-12</sup>

Single Ingredient Products

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Limitations of Use</th>
<th>Dosage</th>
</tr>
</thead>
</table>
| **Altoprev**<sup>®</sup> (lovastatin extended release) tablets | Adjunctive therapy to diet to:  
- Reduce the risk of MI, revascularization procedures, and angina in patients without CHD, but with multiple risk factors.  
- Slow the progression of coronary atherosclerosis in patients with CHD as part of a treatment strategy to lower Total-C and LDL-C.  
- Reduce elevated Total-C, LDL-C, Apo B, and TG levels and increase HDL-C in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia. | Not studied in Fredrickson Types I, III, and V dyslipidemias. | 20-60 mg once daily |
<table>
<thead>
<tr>
<th>Drug</th>
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<th>Limitations of Use</th>
<th>Dosage</th>
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</thead>
</table>
| **Crestor®** *(rosuvastatin)* tablets | • Patients with primary hyperlipidemia and mixed dyslipidemia as an adjunct to diet to reduce elevated total-C, LDL-C, ApoB, nonHDL-C, and TG levels and to increase HDL-C  
• Patients with hypertriglyceridemia as an adjunct to diet  
• Patients with primary dysbeta-lipoproteinemia (Type III hyperlipoproteinemia) as an adjunct to diet  
• Patients with homozygous familial hypercholesterolemia (HoFH) to reduce LDL-C, total-C, and ApoB  
• Slowing the progression of atherosclerosis as part of a treatment strategy to lower total-C and LDL-C as an adjunct to diet  
• Pediatric patients 10 to 17 years of age with heterozygous familial hypercholesterolemia (HeFH) to reduce elevated total-C, LDL-C and ApoB after failing an adequate trial of diet therapy  
• Risk reduction of MI, stroke, and arterial revascularization procedures in patients without clinically evident CHD, but with multiple risk factors | Not studied in Fredrickson Type I and V dyslipemias. | 5-40 mg once daily |
| **Lescol®** *(fluvastatin)* capsules | Adjunctive therapy to diet to:  
• Reduce elevated TC, LDL-C, Apo B, and TG, and to increase HDL-C in adult patients with primary hypercholesterolemia and mixed dyslipidemia  
• Reduce elevated TC, LDL-C, and Apo B levels in boys and post-menarchal girls, 10 to 16 years of age, with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy  
• Reduce the risk of undergoing revascularization procedures in patients with clinically evident CHD  
• Slow the progression of atherosclerosis in patients with CHD | Not studied in conditions where the major abnormality is elevation of chylomicrons, VLDL, or IDL (i.e., hyperlipoproteinemia Types I, III, IV, or V) | 40 mg to 80 mg once daily or in two divided doses |
| **Lescol XL®** *(fluvastatin)* tablets ER | Adjunct therapy to diet to:  
• Reduce the risk of MI, stroke, revascularization procedures, and angina in patients without CHD, but with multiple risk factors  
• Reduce the risk of MI and stroke in patients with type 2 diabetes without CHD, but with multiple risk factors  
• Reduce the risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF, and angina in patients with CHD  
• Reduce elevated total-C, LDL-C, apo B, and TG levels and increase HDL-C in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia  
• Reduce elevated TG in patients with hypertriglyceridemia and primary dysbeta-lipoproteinemia  
• Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH)  
• Reduce elevated total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy | Not studied in Fredrickson Types I and V dyslipemias. | 80 mg once daily |
| **Lipitor®** *(atorvastatin)* tablets | Adjunct therapy to diet to:  
• Reduce the risk of MI, stroke, revascularization procedures, and angina in patients without CHD, but with multiple risk factors  
• Reduce the risk of MI and stroke in patients with type 2 diabetes without CHD, but with multiple risk factors  
• Reduce the risk of non-fatal MI, fatal and non-fatal stroke, revascularization procedures, hospitalization for CHF, and angina in patients with CHD  
• Reduce elevated total-C, LDL-C, apo B, and TG levels and increase HDL-C in adult patients with primary hyperlipidemia (heterozygous familial and nonfamilial) and mixed dyslipidemia  
• Reduce elevated TG in patients with hypertriglyceridemia and primary dysbeta-lipoproteinemia  
• Reduce total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH)  
• Reduce elevated total-C, LDL-C, and apo B levels in boys and postmenarchal girls, 10 to 17 years of age, with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy | Not studied in Fredrickson Types I and V dyslipemias. | 10-80 mg once daily |
<table>
<thead>
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<tbody>
<tr>
<td><strong>Livalo® (pitavastatin)</strong> tablets</td>
<td>Patients with primary hyperlipidemia or mixed dyslipidemia as an adjunctive therapy to diet to reduce elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG), and to increase high-density lipoprotein cholesterol (HDL-C).</td>
<td>- Doses of LIVALO greater than 4 mg once daily were associated with an increased risk for severe myopathy in premarketing clinical studies. Do not exceed 4 mg once daily dosing of LIVALO. The effect of LIVALO on cardiovascular morbidity and mortality has not been determined. LIVALO has not been studied in Fredrickson Type I, III, and V dyslipidemias.</td>
<td>1-4 mg once daily</td>
</tr>
<tr>
<td><strong>Mevacor® (lovastatin)</strong> tablets</td>
<td>Adjunctive therapy to diet for: • Primary prevention of coronary heart disease • To slow the progression of coronary atherosclerosis in patients with coronary heart disease as part of a treatment strategy to lower total-C and LDL-C to target levels. • Reduction of elevated total-C and LDL-C levels in patients with primary hypercholesterolemia (Types IIa and IIb2) • To reduce total-C, LDL-C and apolipoprotein B levels in adolescent boys and girls who are at least one year postmenarche, 10-17 years of age, with Heterozygous Familial Hyperlipidemia</td>
<td>Not studied in conditions where the major abnormality is elevation of chylomicrons, VLDL or LDL (i.e., hyperlipoproteinemia types I, III, IV, or V).</td>
<td>10 mg to 80 mg daily in single or two divided doses</td>
</tr>
<tr>
<td><strong>Pravachol® (pravastatin)</strong> tablets</td>
<td>Adjunctive therapy to diet to: • Reduce the risk of MI, revascularization, and cardiovascular mortality in hypercholesterolemic patients without clinically evident CHD. • Reduce the risk of total mortality by reducing coronary death, MI, revascularization, stroke/TIA, and the progression of coronary atherosclerosis in patients with clinically evident CHD. • Reduce elevated Total-C, LDL-C, ApoB, and TG levels and to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia. • Reduce elevated serum TG levels in patients with hypertriglyceridemia. • Treat patients with primary dysbeta-lipoproteinemia who are not responding to diet. • Treat children and adolescent patients ages 8 years and older with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy</td>
<td>Not studied in Fredrickson Types I and V dyslipidemias.</td>
<td>10 mg to 80 mg once daily</td>
</tr>
<tr>
<td>Drug</td>
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<td>Dosage</td>
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</table>
| Zocor* Δ (simvastatin) tablets | Adjunctive therapy to diet to:  
• Reduce the risk of total mortality by reducing CHD deaths and reduce the risk of non-fatal myocardial infarction, stroke, and the need for revascularization procedures in patients at high risk of coronary events.  
• Reduce elevated total-C, LDL-C, Apo B, TG and increase HDL-C in patients with primary hyperlipidemia (heterozygous, familial, and nonfamilial) and mixed dyslipidemia.  
• Reduce elevated TG in patients with hypertriglyceridemia and reduce TG and VLDL-C in patients with primary dysbeta-lipoproteinemia.  
• Reduce total-C and LDL-C in adult patients with homozygous familial hypercholesterolemia.  
• Reduce elevated total-C, LDL-C, and Apo B in boys and postmenarchal girls, 10 to 17 years of age with heterozygous familial hypercholesterolemia after failing an adequate trial of diet therapy. | Not studied in Fredrickson Types I and V dyslipidemias. | 5 mg to 80 mg once daily |

* Excluded Drug in some member contracts.  
* Generic available

**Combination Products**

<table>
<thead>
<tr>
<th>Drug</th>
<th>Indication</th>
<th>Limitations of Use</th>
<th>Dosage</th>
</tr>
</thead>
</table>
| Advicor (niacin ER/ lovastatin) tablets | Indicated for treatment when both niacin ER and lovastatin is appropriate:  
Niacin ER  
• Adjunct to diet for reduction of elevated TC, LDL-C, Apo B and TG levels, and to increase HDL-C in patients with primary hypercholesterolemia (heterozygous familial and nonfamilial) and mixed dyslipidemia  
• In patients with a history of myocardial infarction and hypercholesterolemia, niacin is indicated to reduce the risk of recurrent nonfatal myocardial infarction  
• Niacin is also indicated as adjunctive therapy for treatment of adult patients with very high serum triglyceride levels who present a risk of pancreatitis  
Lovastatin  
• Adjunct to diet for the reduction of elevated TC and LDL-C levels in patients with primary hypercholesterolemia  
• Primary prevention of cardiovascular events  
• Secondary prevention of cardiovascular events | 500 mg / 20 mg to 1000 mg / 20 mg once or twice daily |
<table>
<thead>
<tr>
<th>Drug</th>
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<th>Limitations of Use</th>
<th>Dosage</th>
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<tbody>
<tr>
<td><strong>Liptruzet</strong>&lt;br&gt;(ezetimibe/atorvastatin) tablets</td>
<td>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.</td>
<td>• No incremental benefit of ezetimibe/atorvastatin on cardiovascular morbidity and mortality over and above that demonstrated for atorvastatin has been established.  • Ezetimibe/atorvastatin has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.</td>
<td>10 mg / 10 mg to 10 mg / 80 mg once daily</td>
</tr>
<tr>
<td><strong>Simcor</strong>&lt;br&gt;(niacin ER/simvastatin) tablets</td>
<td>• Reduce elevated total-C, LDL-C, Apo B, non-HDL-C, TG, or to increase HDL-C in patients with primary hypercholesterolemia and mixed dyslipidemia when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.  • Reduce TG in patients with hypertriglyceridemia when treatment with simvastatin monotherapy or niacin extended-release monotherapy is considered inadequate.</td>
<td>• No incremental benefit of niacin ER/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin monotherapy and niacin monotherapy has been established.  • Niacin extended-release, one of the components of niacin ER/simvastatin, at doses of 1,500 – 2,000 mg/day, in combination with simvastatin, did not reduce the incidence of cardiovascular events more than simvastatin in a randomized controlled trial of patients with cardiovascular disease and mean baseline LDL-C levels of 74 mg per deciliter.</td>
<td>1000 mg / 20 mg to 2000 mg / 40 mg once daily</td>
</tr>
<tr>
<td><strong>Vytorin</strong>&lt;br&gt;*&lt;br&gt;(ezetimibe/simvastatin) tablets</td>
<td>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</td>
<td>• No incremental benefit of ezetimibe/simvastatin on cardiovascular morbidity and mortality over and above that demonstrated for simvastatin has been established.  • Ezetimibe/simvastatin has not been studied in Fredrickson Type I, III, IV, and V dyslipidemias.</td>
<td>10 mg / 10 mg to 10 mg / 80 mg once daily</td>
</tr>
</tbody>
</table>

* - Generic available  
a - Generic anticipated
POLICY

Prior Authorization Criteria for Approval

Brand Statins will be approved when ANY ONE of the following is met:

1. The patient’s medication history includes use of a generic statin or statin combination in the past 90 days
   OR
2. The patient has a documented intolerance, FDA labeled contraindication, or hypersensitivity to the available generic statin or statin combination products

Length of approval: 12 months

RATIONALE

Statins are recommended to prevent nonfatal and fatal atherosclerotic cardiovascular disease events (ASCVD) [Clinical ASCVD is defined as acute coronary syndromes, or a history of myocardial infarction (MI), or stable or unstable angina, coronary or other arterial revascularization, stroke, transient ischemic attack (TIA), or peripheral arterial disease presumed to be of atherosclerotic origin].\textsuperscript{13} Statin therapy reduces ASCVD events across the spectrum of baseline LDL-C levels $\geq 70$ mg/dL. The relative risk reduction in ASCVD is consistent for primary and secondary prevention and for various subgroups of patients.\textsuperscript{13} Guidelines do not differentiate between the drugs in this class, some patients who experience intolerable myopathies (but have a high benefit to risk ratio for remaining on a statin) switch from one statin to another.\textsuperscript{13,14}

Guidelines

The 2013 American College of Cardiology (ACC) /American Heart Association (AHA) Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic CV Risk in Adults: A Report from the ACC/AHA Task Force on Practice Guidelines safety recommendations for the use of statins in appropriate patients include the following\textsuperscript{13}:

\begin{itemize}
  \item To maximize safety of statins, selection of appropriate statin and dose should be based on patient characteristics, level of ASCVD risk, and potential for adverse effects.
  \item If unexplained or severe muscle symptoms (including pain, tenderness, stiffness, cramping, weakness, or fatigue) occur during statin therapy, promptly discontinue the statin and address the possibility of rhabdomyolysis by evaluating CK, creatinine, and a urinalysis for myoglobinuria.
  \item If mild to moderate muscle symptoms develop during statin therapy, discontinue statin until symptoms are evaluated and symptoms resolve.
    \begin{itemize}
      \item If symptoms resolve, give the patient the original or a lower dose of the same statin to establish a causal relationship between the muscle symptoms and statin therapy.
      \item If a causal relationship exists, discontinue the original statin. Once muscle symptoms resolve, use a low dose of a different statin.
      \item Once a low dose of a statin is tolerated, gradually increase the dose as tolerated.
      \item If, after 2 months without statin treatment, muscle symptoms or elevated CK levels do not resolve, consider other causes of muscle symptoms.
    \end{itemize}
\end{itemize}
If persistent muscle symptoms are determined to arise from a condition unrelated to statin therapy, or if the predisposing condition has been treated, resume statin therapy at the original dose.

### Cholesterol Guidelines

<table>
<thead>
<tr>
<th>High-Intensity Statin Therapy</th>
<th>Moderate-Intensity Statin Therapy</th>
<th>Low-Intensity Statin Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Daily dose lowers LDL-C on average, by $\geq 50%$</td>
<td>Daily dose lowers LDL-C on average, by $\geq 30%$ to $&lt; 50%$</td>
<td>Daily dose lowers LDL-C on average, by $&lt; 30%$</td>
</tr>
<tr>
<td>atorvastatin (40†) - 80 mg</td>
<td>atorvastatin 10 (20) mg</td>
<td>simvastatin 10 mg</td>
</tr>
<tr>
<td>rosuvastatin 20 (40 mg)</td>
<td>rosuvastatin (5) 10 mg</td>
<td>pravastatin 10-20 mg</td>
</tr>
<tr>
<td>simvastatin 20-40 mg‡</td>
<td>pravastatin 40 (80) mg</td>
<td>lovastatin 20 mg</td>
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<tr>
<td>fluvastatin XL 80 mg</td>
<td>fluvastatin 40 mg twice daily</td>
<td>fluvastatin 20-40 mg</td>
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<tr>
<td>fluvastatin 40 mg</td>
<td></td>
<td>pitavastatin 2-4 mg</td>
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</tbody>
</table>

* Individual responses to statin therapy varied in RCTs and should be expected to vary in clinical practice.
† Evidence from 1 RCT only: down titration if unable to tolerate atorvastatin 80 mg in IDEAL study.
‡ Although simvastatin 80 mg was evaluated in RCTs, initiation of simvastatin 80 mg or titration to 80 mg is not recommended by the FDA due to the increased risk of myopathy, including rhabdomyolysis.

According to the American Heart Association (AHA), initial treatment for Familial Hypercholesterolemia should include a high intensity statin.20 If the LDL-C is not at goal after 3 months of therapy with the high intensity statin and the patient has been adherent, AHA recommends the addition of ezetimibe. For patients who do not respond to this two drug regimen within 3 months, AHA recommends addition of a PCKS9, a bile acid sequestrant, or niacin. Patients with HoFH who require additional therapy despite treatment with the three drug regimen, AHA recommends addition of Juxtapid or Kynamro and LDL apheresis.20

The Kidney Disease Improving Global Outcomes (KDIGO) Clinical Practice Guideline for Lipid Management in Chronic Kidney Disease (CKD) [from the International Society of Nephrology] 2013 include the following recommendations:15
- Available evidence argues against the use of LDL-C to identify CKD patients who should receive cholesterol-lowering treatment and suggests focusing instead on two factors: the absolute risk of coronary events, and the evidence that such treatment is beneficial.
- In adults aged $\geq 50$ years with estimated glomerular filtration rate (GFR) $< 60$ ml/min/1.73 m2 but not treated with chronic dialysis or kidney transplantation treatment with a statin or statin/ezetimibe combination is recommended.
- In adults aged 18-49 years with CKD but not treated with chronic dialysis or kidney transplantation, statin treatment in people with one or more of the following conditions is recommended:
  - Known coronary disease (MI or coronary revascularization)
  - DM
  - Prior ischemic stroke
  - Estimated 10-year incidence of coronary death or non-fatal myocardial infarction $> 10\%$.

The National Lipid Association recommends statins as the primary therapy for patients in whom lipid-lowering drug therapy is indicated. Statin therapy should be initiated with a moderate to high intensity statin and dose. Atorvastatin 40-80 mg and rosuvastatin 20-40 mg are
recommended for high intensity therapy. Atorvastatin 10–20 mg, fluvastatin 40 mg twice daily, fluvastatin XL 80 mg, lovastatin 40 mg, pitavastatin 2–4 mg, pravastatin 40–80 mg, rosuvastatin 5–10 mg, simvastatin 20–40 mg are recommended for moderate intensity therapy. Therapy with a statin plus a second (or third) agent may be considered for patients who have not reached their treatment goals for atherogenic cholesterol levels, particularly in patients with very high or high risk. The maximum tolerated statin dosage should generally be used before add-on therapy is considered.¹⁸,¹⁹

Standards of Medical Care in Diabetes 2015 from the American Diabetes Association (AD) recommend the following.¹⁶

- For patients of all ages with DM and overt CVD, high-intensity statin therapy should be added to lifestyle therapy. Intensity depends on co-morbidities.
- In clinical practice, providers may need to adjust intensity of statin therapy based on individual patient response to medication (e.g., side effects, tolerability, LDL cholesterol levels).
- Combination therapy has been shown not to provide additional CV benefit above statin therapy alone and is not generally recommended.
- Statin therapy is contraindicated in pregnancy.

The American Association of Clinical Endocrinologists (AACE) Guidelines for the Management of Dyslipidemia and Prevention of Atherosclerosis 2012 includes the following recommendations:¹⁷

- AACE recommends statins as the drug of choice for LDL-C reduction on the basis of findings from morbidity and mortality outcome trials. Agents currently available are atorvastatin, fluvastatin, lovastatin, pravastatin, rosuvastatin, simvastatin, and pitavastatin.
- Atorvastatin, lovastatin, pravastatin, simvastatin, and rosuvastatin have been approved for the treatment of familial hypercholesterolemia in patients 10 years or older and are recommended by the AACE.

**REVISIONS**

<table>
<thead>
<tr>
<th>Date</th>
<th>Change</th>
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<tbody>
<tr>
<td>01-01-2010</td>
<td>Policy added to the bcbsks.com web site.</td>
</tr>
<tr>
<td>05-20-2011</td>
<td>Added the following target drugs:</td>
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<tr>
<td></td>
<td>Livalo® (pitavastatin)</td>
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<tr>
<td></td>
<td>Description section updated</td>
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<tr>
<td></td>
<td>In Policy section:</td>
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<tr>
<td></td>
<td>Wording clarified from question format to statement format.</td>
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<tr>
<td></td>
<td>Rationale section removed</td>
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<tr>
<td></td>
<td>References section updated</td>
</tr>
<tr>
<td>08-30-2012</td>
<td>Removed &quot;Target Drugs&quot; list and added &quot;FDA Approved Indications and Dosage&quot; chart with Target Drugs listed.</td>
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<td>In Policy section:</td>
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<tr>
<td></td>
<td>Removed the following criteria:</td>
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<tr>
<td></td>
<td>1. The patient has a medical diagnosis that puts patient at a high risk of major coronary event (defined as myocardial infarction, coronary atherosclerosis disease (CAD), stroke, congestive heart failure, diabetes, or a surgical procedure for a coronary stent placement, percutaneous transluminal coronary angioplasty (PTCA), coronary artery bypass graft (CABG), or intracoronary thrombolysis infusion) OR</td>
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<td>3. The patient requires LDL lowering that cannot be achieved with available generic statins*</td>
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<td></td>
<td>*defined as greater than 40% LDL lowering, achievable with simvastatin 40 mg once daily or lovastatin 40 mg twice daily</td>
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### REVISIONS

<table>
<thead>
<tr>
<th>Date</th>
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<tbody>
<tr>
<td>01-01-2013</td>
<td>Policy Title updated from &quot;Statin Step Therapy Prior Authorization Criteria&quot; to &quot;Statin Prior Authorization&quot;&lt;br&gt;<strong>In Description section:</strong>&lt;br&gt;• Updated description&lt;br&gt;• Added Target Drug Brand Statins list&lt;br&gt;<strong>In Policy section:</strong>&lt;br&gt;• Added the word statin to item #1 to read &quot;The patient’s medication history includes use of a generic statin&quot; - This update causes no change to the policy statement meaning.</td>
</tr>
<tr>
<td>07-01-2013</td>
<td>Policy posted July 12, 2013. &lt;br&gt;Added under Prior Authorization Form link &quot;Prime Therapeutics will review Prior Authorization requests.&quot;&lt;br&gt;<strong>Administrative Update:</strong>&lt;br&gt;<strong>In Description section:</strong>&lt;br&gt;• Added Liptruzet (ezetimibe/atorvastatin tabs)</td>
</tr>
<tr>
<td>01-01-2014</td>
<td><strong>In Header:</strong>&lt;br&gt;• Revised Title from &quot;Statin Prior Authorization&quot; to &quot;Statin Therapy&quot;&lt;br&gt;<strong>Description section updated</strong>&lt;br&gt;<strong>In Policy section:</strong>&lt;br&gt;• In Items 1 and 2 added &quot;or statin combination&quot;&lt;br&gt;• In item 1 added look-back information&lt;br&gt;<strong>Rationale section updated</strong>&lt;br&gt;<strong>Coding section added</strong>&lt;br&gt;<strong>References updated</strong></td>
</tr>
<tr>
<td>10-28-2014</td>
<td><strong>Description section updated</strong>&lt;br&gt;<strong>Rationale section updated</strong>&lt;br&gt;<strong>Coding section removed as codes are not used for pharmacy benefit.</strong>&lt;br&gt;<strong>References updated</strong></td>
</tr>
<tr>
<td>10-01-2015</td>
<td>Published 09-16-2015. Effective 10-01-2015.&lt;br&gt;<strong>Updated Description section to include:</strong>&lt;br&gt;• Reformating of FDA Approved Indications and Dosage chart&lt;br&gt;• Added indication of &quot;Excluded Drug in some member contracts&quot;&lt;br&gt;<strong>Rationale section updated</strong>&lt;br&gt;<strong>References updated</strong></td>
</tr>
<tr>
<td>09-01-2016</td>
<td><strong>In Description section</strong>&lt;br&gt;<strong>Updated keys in Target Drugs list and FDA Approved Indications and Dosage chart</strong>&lt;br&gt;<strong>In Policy section:</strong>&lt;br&gt;• In Item 1 removed “(evidence of a paid claim within the past 90 days, or patient is new to the claim system within the past 120 days AND a statement by the physician that patient has taken a generic statin agent in the past 90 days)” and added “in the past 90 days” to read “The patient’s medication history includes use of a generic statin or statin combination in the past 90 days”&lt;br&gt;<strong>Rationale section updated</strong>&lt;br&gt;<strong>References updated</strong></td>
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*Contains Public Information*
REFERENCES