STATIN UTILIZATION MANAGEMENT CRITERIA

DRUG CLASS: HMG Co-A Reductase Inhibitors & Combinations

<table>
<thead>
<tr>
<th>Agents which require prior review:</th>
<th>Agents which do NOT require prior review:</th>
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<tbody>
<tr>
<td>• Advicor® (niacin extended-release/lovastatin)</td>
<td>• Atorvastatin (Lipitor®)</td>
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<tr>
<td>• Lescol XL® (fluvastatin)</td>
<td>• Crestor® (rosuvastatin)</td>
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<td>• Liptruzet™ (ezetimibe/atorvastatin)</td>
<td>• Fluvastatin (Lescol®)</td>
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<td>• Livalo® (pitavastatin)</td>
<td>• Lovastatin (Mevacor®, Altoprev®)</td>
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<tr>
<td>• Simcor® (niacin extended-release/simvastatin)</td>
<td>• Pravastatin (Pravachol®)</td>
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<tr>
<td>• Vytorin® (ezetimibe/simvastatin)</td>
<td>• Simvastatin (Zocor®)</td>
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COVERAGE AUTHORIZATION CRITERIA:
Advicor
Lescol XL
Liptruzet
Livalo
Simcor
Vytorin

Patient must meet at least ONE of the following criteria below:

1. Patient has tried at least one generically available statin (e.g., lovastatin, pravastatin, simvastatin, fluvastatin, or atorvastatin) or brand Crestor; OR

2. For patients requesting combination products (i.e., Vytorin, Simcor, Liptruzet or Advicor); patient has medical record documentation that they are stable on both components of the combination product; AND

3. For members on the Basic Open Formulary, before approval of a nonpreferred agent is given, two preferred agents must be tried. Please consult the formulary list as these agents may change over time.

FDA-APPROVED INDICATIONS:
Liptruzet™:
• 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.

Last Revision Date: March 2015
Livalo:<ul><li>Patients with primary hyperlipidemia and 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)</li></ul>

Lescol XL:<ul><li>Reduce elevated TC, LDL-C, Apo B, and TG, and to increase HDL-C in adult patients with primary hypercholesterolemia and mixed dyslipidemia.</li><li>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.</li><li>Reduce the risk of undergoing revascularization procedures in patients with clinically evident CHD.</li><li>Slow the progression of atherosclerosis in patients with CHD.</li></ul>

Vytorin:<ul><li>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.</li><li>Reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid lowering treatments.</li></ul>

Simcor:<ul><li>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.</li><li>Reduce elevated total-C and LDL-C in patients with homozygous familial hypercholesterolemia (HoFH), as an adjunct to other lipid lowering treatments.</li></ul>

Advicor:<ul><li>Use when treatment with both Niaspan® and lovastatin is appropriate:<ul><li>Lovastatin:<ul><li>Adjunct to diet for the reduction of elevated TC and LDL-C levels in patients with primary hypercholesterolemia, when the response to diet restricted in saturated fat and cholesterol and to other nonpharmacological measures alone has been inadequate</li><li>In individuals without symptomatic cardiovascular disease, average to moderately elevated TC and LDL-C, and below average HDL-C, lovastatin is indicated to reduce the risk of:<ul><li>Myocardial infarction</li><li>Unstable angina</li><li>Coronary revascularization procedures</li></ul></li><li>Slow the progression of coronary atherosclerosis in patients with coronary heart disease as part of a treatment strategy to lower TC and LDL-C to target levels.</li></ul></li></li></ul></li><li>Niaspan (niacin extended-release)<ul><li>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 and mixed dyslipidemia, when the response to an appropriate diet has been inadequate.</li></ul></li></ul>
In patients with a history of myocardial infarction and hypercholesterolemia, niacin is indicated to reduce the risk of recurrent nonfatal myocardial infarction.

Adjunctive therapy for treatment of adult patients with very high serum triglyceride levels who present a risk of pancreatitis and who do not respond adequately to a determined dietary effort to control them.

**DOSAGE AND ADMINISTRATION:**

Livalo dosing can range from 1 mg to 4 mg orally once daily.\(^2\)

Lescol XL dosing can range from 20 mg to 80 mg orally once daily.

Vytorin dosing is 10/10 mg/day to 10/40 mg/day orally once daily. Recommended usual starting dose is 10/10 or 10/20 mg/day.\(^3\)

Simcor dosing is 500/20mg to 2000/40mg orally once daily. Recommended starting dose for niacin naïve to or switching to immediate-release niacin patients is 500/20mg.\(^4\)

Advicor should be taken orally at bedtime. Dosing should be initiated at 500/20mg, and every 4 weeks be increased by 500mg but should not exceed 2000/40mg daily.\(^5\)

Lipitor dosing can range from 10 to 80 mg once daily. Patients requiring large LDL-C reduction (>45%) may start at 40 mg once daily.\(^6\)

Pravachol dosing can range from 10 to 80mg once daily. The recommended starting dose is 40 mg once daily. Use 80 mg dose only for patients not reaching LDL-C goal with 40 mg.\(^9\)

Zocor dosing can range from 5 to 40 mg once daily. Recommended usual starting dose is 10 or 20 mg once a day in the evening. Recommended starting dose for patients at high risk of CHD is 40 mg per day.\(^10\)

Mevacor dosing can range from 10 to 80mg per day in once or twice daily dosing. The usual recommended starting dose is 20 mg once a day given with the evening meal. The maximum recommended dose is 80 mg/day.\(^11\)

Liptruzet dosage range is 10/10 mg/day through 10/80 mg/day. Recommended starting dose is 10/10 mg/day or 10/20 mg/day.
## Table VI.1–3. Drug Therapy Consideration and Goals of Therapy for Primary Prevention

<table>
<thead>
<tr>
<th>Risk Category</th>
<th>10-Year Risk for CHD</th>
<th>LDL Cholesterol</th>
<th>Level at Which to Consider Drug Therapy</th>
<th>Primary Goal of Therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Multiple (2+) risk factors</td>
<td>&gt;20% (includes all CHD Risk Equivalents*)</td>
<td>&gt;100 mg/dL†</td>
<td>&lt;100 mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10-20%</td>
<td>≥130 mg/dL‡</td>
<td>&lt;130 mg/dL</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&lt;10%</td>
<td>≥160 mg/dL</td>
<td>&lt;130 mg/dL</td>
<td></td>
</tr>
<tr>
<td>0-1 risk factor</td>
<td>&lt;10%</td>
<td>≥190 mg/dL¥</td>
<td>&lt;160 mg/dL</td>
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</tr>
</tbody>
</table>

Non-lipid risk factors include: obesity, diabetes, smoking, and hypertension

Primary Prevention risk factors include: Age (Men ≥ 45 years old, Women ≥ 55 years old), family history of premature CHD, current cigarette smoking, hypertension, low HDL cholesterol (<40 mg/dL)

Negative (protective) Risk Factor: High HDL cholesterol (≥60 mg/dL)

* Most patients with CHD risk equivalents have multiple risk factors and a 10-year risk >20 percent. They include patients with non-coronary forms of clinical atherosclerosis, diabetes, and multiple (2+) risk factors with a 10-year risk >20 percent by Framingham scoring.
† When LDL cholesterol is ≥130 mg/dL, a cholesterol-lowering drug can be started concomitantly with TLC. If baseline LDL cholesterol is 100–129 mg/dL, TLC should be started immediately. Concomitant use of drugs is optional; several options for drug therapy are available (e.g., statins, bile acid sequestrants, fibrates, nicotinic acid).
‡ When LDL cholesterol is in the range of 130–159 mg/dL, drug therapy can be used if necessary to reach the LDL-cholesterol goal of <130 mg/dL, after an adequate trial of TLC.
¥ When LDL cholesterol is in the range of 160–189 mg/dL, use of cholesterol-lowering drugs is optional, depending on response to TLC diet.

**REFERENCES:**

1. Livalo [package insert], Montgomery, AL: Kowa Pharmaceuticals
2. Vytorin [package insert], North Wales, PA: Merck/ Schering-Plough Pharmaceuticals
5. Lescol [package insert]. East Hanover, NJ: Novartis Pharmaceuticals