2013 ACC/AHA Cholesterol Guidelines

The 2013 American Heart Association (AHA)/American College of Cardiology (ACC) lipid guidelines represent a paradigm shift in the treatment of dyslipidemia. These guidelines focus on reducing cardiovascular risk using proven interventions. Per the new guidelines, patients receive high- or moderate-dose statin therapy, depending on which of four “statin benefit groups” they fit into. The guidelines introduce a new risk calculator for estimation of 10-year cardiovascular disease risk. This calculator can be used to determine if a high- or moderate-dose statin is appropriate for primary prevention. Unlike previous guidelines, the 2013 guidelines do not recommend titrating the statin dose to achieve a specific LDL target. This is because randomized controlled trials have demonstrated cardiovascular risk reduction using specific statin doses, not LDL targets. Treating to a given target may result in statin undertreatment if an evidence-based statin dose is not used, or overtreatment. The addition of a nonstatin has not been proven to further reduce cardiovascular risk; therefore, nonstatins are no longer routinely recommended. The table below provides a summary of these guidelines, with an emphasis on pharmacotherapy.

--Information in table is from reference 1 unless otherwise denoted.--

<table>
<thead>
<tr>
<th>Who should be assessed for cardiovascular risk, and how?</th>
<th>For patients without atherosclerotic cardiovascular disease:</th>
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<tbody>
<tr>
<td></td>
<td>- Assess traditional risk factors (e.g., lipids, blood pressure, diabetes) every four to six years in patients 20 to 79 years of age.¹,²,³</td>
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<td>- In patients 40 to 75 years of age not receiving cholesterol-lowering therapy, and with LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L), also estimate 10-year risk using the Pooled Cohort Equations Cardiovascular Risk Calculator, available at <a href="http://my.americanheart.org/cvriskcalculator">http://my.americanheart.org/cvriskcalculator</a>. Get an app from iTunes (for iPhone, iPad, and iPod), or Google Play (for Android).</td>
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<tr>
<th>What lifestyle changes are recommended to reduce cardiovascular risk?</th>
<th>Adhere to a heart-healthy diet:</th>
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<td>- Eat vegetables, fruits, whole grain, low-fat dairy, poultry, fish, beans, nontropical vegetable oils, and nuts, but avoid red meat (i.e., Mediterranean-style diet, DASH [Dietary Approaches to Stop Hypertension] diet).²</td>
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<td>- Limit sugary drinks and sweets.²</td>
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<td></td>
<td>- Limit saturated and trans fat to 5% to 6% of calories.²</td>
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<td></td>
<td>- Limit sodium intake to 2400 mg daily (about one teaspoon table salt [kosher/sea salt have less sodium per teaspoon]).²</td>
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<td>- For adults who would benefit from blood pressure lowering, further reduction to 1500 mg daily is ideal. Combine sodium restriction with the DASH diet.²</td>
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<td>Exercise regularly:</td>
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<td>- Engage in moderate-to-vigorous aerobic activity for at least 40 minutes (on average) three to four times each week.²</td>
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<td>Avoid tobacco.</td>
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<td>Maintain a healthy weight.</td>
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Who should be treated with a statin?

There are four major statin benefit groups:
- Patients with clinical atherosclerotic cardiovascular disease.
- Patients with LDL 190 mg/dL (5 mmol/L) or higher.
- Patients age 40 to 75 years of age with diabetes (but without clinical atherosclerotic cardiovascular disease) and LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L).
- Patients without clinical atherosclerotic cardiovascular disease or diabetes with LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L), with an estimated 10-year risk of atherosclerotic cardiovascular disease of 7.5% or higher.

If a patient does not fit into one of the four statin benefit groups (e.g., LDL 70 to 189 mg/dL [1.8 to 4.9 mmol/L] with 10-year risk 5% to 7.5%), but there is clinical suspicion that they may benefit from a statin, additional factors can be taken into consideration:
- LDL 160 mg/dL or higher or other evidence of genetic hyperlipidemia.
- Cardiovascular disease onset in a first degree male relative before age 55, or in a first degree female relative before age 65.
- High-sensitivity C-reactive protein 2 mg/dL or higher.
- Ankle-brachial index <0.9.
- Elevated lifetime risk of atherosclerotic cardiovascular disease.
- Coronary artery calcium (CAC) score 300 Agatston units or higher, or 75th percentile or higher for age, gender, and ethnicity.
- Statin adverse effects.
- Statin drug interactions.
- Patient preferences.

What are the pharmacologic treatment options?

Pharmacotherapy

High-dose Statin (average LDL reduction about 50% or higher):
- Atorvastatin 80 mg once daily (40 mg if 80 mg not tolerated).
- Rosuvastatin 20 mg to 40 mg once daily.

Use for...

- Secondary prevention in adults 75 years of age and younger. (Level A)
- Primary prevention in adults with LDL 190 mg/dL (5 mmol/L) or higher. (Level A)
- Primary prevention in adults 40 to 75 years of age with LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L) and an estimated 10-year risk of atherosclerotic cardiovascular disease of 7.5% or higher (moderate-dose also an option). (Level A)
- Primary prevention in diabetes patients 40 to 75 years of age with LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L) and an estimated 10-year risk of atherosclerotic cardiovascular disease of 7.5% or higher. (Level C)

Continued…
Pharmacologic treatment options, continued

<table>
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<tr>
<th>Pharmacologic Treatment Options</th>
<th>Pharmacotherapy</th>
<th>Use for…</th>
</tr>
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</table>
| **Moderate-dose Statin** (average LDL reduction about 30 to <50%):<sup>a</sup> | • Atorvastatin 10 to 20 mg once daily.<sup>b</sup>  
• Fluvastatin 40 mg twice daily or 80 mg (XL) once daily.<sup>b</sup>  
• Lovastatin 40 mg once daily.  
• Pitavastatin 2 to 4 mg once daily.<sup>b</sup>  
• Pravastatin 40 to 80 mg once daily.<sup>b</sup>  
• Rosuvastatin 5 to 10 mg once daily.<sup>b</sup>  
• Simvastatin 20 to 40 mg once daily. | • Secondary prevention in adults older than 75 years. (Level A)  
• Patients who cannot tolerate a high-dose statin.  
• Primary prevention in adults 40 to 75 years of age with LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L) and an estimated 10-year risk of atherosclerotic cardiovascular disease of 7.5% or higher (high-dose also an option). (Level A)  
• Primary prevention in diabetes patients 40 to 75 years of age, with LDL 70 to 189 mg/dL (1.8 to 4.9 mmol/L) and an estimated 10-year risk of atherosclerotic cardiovascular disease of less than 7.5%. (Level A) |
| **Low-dose Statin** (average LDL reduction <30%):<sup>a</sup> | • Fluvastatin 20 to 40 mg once daily.<sup>b</sup>  
• Lovastatin 20 mg once daily.  
• Pitavastatin 1 mg once daily.<sup>b</sup>  
• Pravastatin 10 to 20 mg once daily.  
• Simvastatin 10 mg once daily.<sup>b</sup> | • For patients who cannot tolerate a high- or moderate-dose statin. |
| **Nonstatin** | • Reinforce statin adherence and lifestyle changes, and check for secondary causes before adding a nonstatin.  
• Do not add gemfibrozil to statin therapy.  
• No proof adding a nonstatin to a statin further reduces cardiovascular risk. | • Triglycerides 500 mg/dL or higher (use omega-3 fatty acids [e.g., fish oil], niacin, or fenofibrate).  
• Patients who cannot tolerate the recommended statin dose or do not achieve the expected statin response and are high-risk (i.e., patient with LDL 190 mg/dL [5 mmol/L] or higher at baseline, diabetes, or clinical atherosclerotic cardiovascular disease). |

How is statin therapy monitored?  

Continued…

- Check ALT (alanine aminotransferase) at baseline. Repeat only if symptoms of hepatotoxicity occur.  
- Document any pre-existing muscle symptoms before starting a statin to establish a baseline.  
- Consider checking creatine kinase at baseline in patients at increased risk for myopathy (e.g., drug interactions, etc). Repeat only if symptomatic.  
- If severe muscle symptoms or fatigue of unknown cause develop, hold the statin and check creatinine and urinalysis to rule-out rhabdomyolysis.
**Statin monitoring, continued**

- Check fasting lipid panel four to 12 weeks after statin initiation, then every three to 12 months.
  - Check adherence to statin and lifestyle interventions if LDL drop less than expected.
  - Consider statin dose reduction if two consecutive LDL measurements are less than 40 mg/dL (1.03 mmol/L).
  - Monitor for new-onset diabetes per diabetes screening guidelines.

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- **a.** Doses listed are for patients with normal renal function not taking an interacting medication. See our *PL Chart, Characteristics of the Various Statins*, for renal dosing and select drug interactions. High-dose, moderate-dose, and low-dose statin designations are categorical only. Actual statin percent LDL-lowering may vary in practice.
- **b.** Atorvastatin 20 mg, fluvastatin extended-release (XL) 80 mg, fluvastatin 20 to 40 mg, pitavastatin, pravastatin 80 mg, rosuvastatin 5 mg and 40 mg, and simvastatin 10 mg are FDA-approved but lack evidence from randomized-controlled trials for reduction in major cardiovascular events.

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### Levels of Evidence

In accordance with the trend towards Evidence-Based Medicine, we are citing the **LEVEL OF EVIDENCE** for the statements we publish.

<table>
<thead>
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<th>Level</th>
<th>Definition</th>
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| A     | High-quality randomized controlled trial (RCT)  
STRUCTION systematic review) |
| B     | Nonrandomized clinical trial  
NONquantitative systematic review  
Lower quality RCT  
Clinical cohort study  
Case-control study  
Historical control  
Epidemiologic study |
| C     | Consensus  
Expert opinion |
| D     | Anecdotal evidence  
In vitro or animal study |


### Project Leader in preparation of this PL Detail-Document: Melanie Cupp, Pharm.D., BCPS

### References


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