The Cholesterol Management Development Team, under the guidance of Intermountain’s Primary Care and Cardiovascular Clinical Programs, developed this care process model (CPM) to guide the effective, consistent management of cholesterol levels for patients across the Intermountain system. This CPM is based on the 2013 American College of Cardiology and the American Heart Association (ACC/ AHA) Guideline on the Assessment of Cardiovascular Risk,\textsuperscript{GOF} the 2013 ACC/AHA Guideline on Lifestyle Management to Reduce Cardiovascular Risk,\textsuperscript{ECK} and the 2017 ACC Expert Document.\textsuperscript{LLO}

**Why Focus ON CHOLESTEROL MANAGEMENT?**

- More than 30% of U.S. adults have high LDL cholesterol. Of these, about half are being treated for it.\textsuperscript{JAC,C}
- High cholesterol is a leading risk factor for atherosclerotic cardiovascular disease (ASCVD), heart attack, and stroke.
- New guidelines published in 2013 by a joint task force of the ACC/AHA provides higher quality randomized controlled trial (RCT) evidence for cholesterol-lowering drug therapy to reduce ASCVD risk. In addition, the ACC endorsed updated guidelines incorporating new evidence in 2017.
- People with diabetes who are currently taking statins will be added as a STARS measure, effective in 2019.

**Key points from the updated guidelines**

- Lifestyle modification remains the foundation of ASCVD risk reduction. Heart-healthy lifestyle habits are recommended for all patients, whether or not they are on statin therapy.
- “Treat to target” has been reevaluated. The 2013 ACC/AHA guidelines do not endorse treating to specific levels and instead support appropriate intensity of statin therapy and percent or LDL-C reductions. Other guidelines, including the National Lipid Association (NLA), American Association of Endocrinology (AACE), the 2017 Expert Consensus Document (as well as many experts within Intermountain) feel there may be a role for levels in certain instances (see page 4).\textsuperscript{JAC,EL,LLO}
- Four groups of individuals are identified as most likely to benefit from statin therapy. These include those diagnosed with clinical ASCVD, those age 40 to 75 with diabetes, patients with a baseline LDL > 190 mg/dL, and those with a calculated 10-year ASCVD risk of > 7.5%. See page 2.
- The new Pooled Cohort Risk Calculator evaluates 10-year and lifetime risk of ASCVD and more accurately identifies higher-risk patients who may benefit from statin therapy. This can be found in iCentra in the Calculators section under the title, ACC/AHA 2013 Cardiovascular Risk Assessment.
- Shared decision making on statin therapy is recommended for primary prevention in patients at lower risk but who have additional risk factors.
ALGORITHM: ASSESSMENT AND MANAGEMENT OF CHOLESTEROL LEVELS AND ASCVD RISK

ASCVD Risk Reduction For All Patients (a)

SCREEN all adults age ≥ 20 years with full lipoprotein panel (fasting preferred) once every 5 years

no

Clinical ASCVD? (b) yes Age ≤ 75?

no yes

LDL-C ≥ 190 mg/dL?

no yes

Diabetes? (For patients age 20 to 39 or > 75, see sidebar on page 4)

no yes

Age 40 to 75?

no yes

CONSIDER additional factors (e) in select individuals to inform treatment decision making

EVALUATE 10-year risk

• ESTIMATE 10-year ASCVD risk every 5 years beginning at age 20 using Pooled Cohort Equation
• SUPPORT primary prevention (d)

<table>
<thead>
<tr>
<th>10-year ASCVD risk &lt; 7.5%</th>
<th>10-year ASCVD risk ≥ 7.5%</th>
</tr>
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</table>

CONSIDER moderate-intensity statin
(Note: High-intensity statin may be indicated if higher % risk, greater LDL reduction desired, or additional risk factors) (e)(f)

ENGAGE patient in shared decision-making discussion regarding statin use

NO to statin

• EMPHASIZE lifestyle, and MONITOR adherence
• MANAGE other risk factors

YES to statin

• EMPHASIZE lifestyle, and MONITOR adherence and response with serial lipid-panel measurements
• INITIATE statin at appropriate intensity and MONITOR adherence
• MANAGE other risk factors

Indicates an Intermountain measure
### ALGORITHM NOTES

#### (a) ASCVD risk reduction for all patients

The 2013 AHA/ACC Lifestyle Management Guidelines recommend the following lifestyle habits (see page 5).¹³

- **Heart-healthy diet**: To manage LDL-cholesterol, and, if necessary, blood pressure (DASH, Mediterranean, or Cardiac diet)
- **Physical activity**: Moderate- to vigorous-intensity physical activity totalling 150 minutes per week (about 30 minutes most days)
- **Tobacco cessation**: Quit all tobacco products, and avoid second-hand smoke
- **Weight management**: Reach and maintain a normal weight

#### (b) Clinical ASCVD

Clinical ASCVD is defined as one or more of the following:

- Acute coronary syndromes
- History of MI
- Stable or unstable angina
- Coronary or other arterial revascularization
- Atherosclerotic stroke
- Atherosclerotic TIA
- Atherosclerotic peripheral artery disease
- Abdominal aortic aneurysm

#### (c) Statin Therapy Recommendations

**Do not prescribe if patient is pregnant or lactating**

<table>
<thead>
<tr>
<th>High-intensity statin therapy</th>
<th>Moderate-intensity statin therapy</th>
<th>Low-intensity statin therapy</th>
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<tbody>
<tr>
<td>Patients with ANY of these:</td>
<td>Patients with ANY of these:</td>
<td>Patients with ANY of these:</td>
</tr>
<tr>
<td>- Clinical ASCVD AND &lt;75 years</td>
<td>- Clinical ASCVD AND &gt;75 years</td>
<td>- &lt;7.5 % 10-year ASCVD risk AND other risk factors</td>
</tr>
<tr>
<td>- LDL-C &gt; 190</td>
<td>- Diabetes AND age 20 to 39 OR &gt; 75 years</td>
<td>- Diabetes AND age 20–39 with a 30–40 % lifetime ASCVD risk</td>
</tr>
<tr>
<td>- Diabetes AND 40 to 75 years</td>
<td>- 10-year ASCVD risk is ≥ 7.5%</td>
<td>- Intolerance to higher-intensity statins</td>
</tr>
<tr>
<td>- ≥7.5 % 10-year ASCVD risk</td>
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</tbody>
</table>

Daily dose lowers LDL-C on average by approximately 50 % or more*  
Daily dose lowers LDL-C on average by approximately 30 % to 50 %*  
Daily dose lowers LDL-C on average by up to 30 %

- **atorvastatin (40**) to 80 mg
- **rosuvastatin 20 (40) mg**
- **atorvastatin 10 (20) mg**
- **simvastatin 20 mg to 40 mg**
- **pravastatin 40 (80) mg**
- **lovastatin 40 mg**
- **fluvastatin XL 80 mg**
- **fluvastatin 40 mg bid**
- **pitavastatin 2 mg to 4 mg**
- **rosuvastatin (5) 10 mg**
- **pravastatin 10 mg to 20 mg**
- **lovastatin 20 mg**
- **simvastatin 10 mg**
- **fluvastatin 20 mg to 40 mg**
- **pitavastatin 1 mg**

**Notes:**

- **Boldface type** indicates preferred drug.
- **Prior to initiating drug therapy,** evaluate patient for secondary causes of dyslipidemia, which include diabetes, hypothyroidism, obstructive liver disease, nephrotic syndrome, CKD, malnourishment, anorexia, or drugs that increase LDL-C and decrease HDL-C (progestins, anabolic steroids, and corticosteroids).
- **Beware of drug interactions** with atorvastatin (80 mg) and simvastatin (40 mg), including clarithromycin, erythromycin, amiodarone, calcium channel blockers, or fluconazole.

* Individual responses to statin therapy should be expected to vary in clinical practice. There may be a biologic basis for less-than-average response.

** Evidence from one RCT only: down-titration if unable to tolerate atorvastatin 80 mg in IDEAL.²²

#### (d) Primary prevention in patients without diabetes and with LDL-C 70 – 189 mg/dL

- EMPHASIZE adherence to a heart-healthy lifestyle.
- CHECK fasting lipid profile every five years.
- For patients age 40 to 75 years, ESTIMATE 10-year ASCVD risk every five years, beginning at age 20, and CHOOSE appropriate statin therapy. Use the Pooled Cohort Equations available at tools.cardiosource.org/ASCVD-Risk-Estimator.
- For patients <40 years or >75 years and LDL-C < 190 mg/dL, CONSIDER additional factors and MAKE SHARED DECISION on statin use.

#### (e) Additional ASCVD risk factors (beyond those included in the pooled cohort equation)

When unsure whether or not to prescribe a statin, CONSIDER:

- Family history of premature ASCVD
- Chronic kidney disease stage 3 or 4
- Coronary artery calcium (CAC) score ≥ 300 Agatston units or ≥ 90th percentile for age and sex
- Ankle brachial index (ABI) < 0.9
- hs-CRP ≥ 2.0 mg/L
- Metabolic syndrome or prediabetes

#### (f) Shared decision making on statin use

Prior to initiating statin therapy, DISCUSS with patient:

- Potential for ASCVD risk reduction benefit from statin therapy
- Potential for adverse effects and drug interactions from statin therapy
- Role of therapeutic lifestyle change
- Management of other risk factors such as blood pressure, diabetes, and abdominal obesity
- Risk of pregnancy
- Patient preferences
DIABETES AND AGE 20 TO 39 OR > 75: INTERMOUNTAIN RECOMMENDATIONS

For patients with diabetes who are outside the 40–75 age range, the AHA/ACC did not have enough data to make clear recommendations. Intermountain experts in cardiology and primary care recommend shared decision making with patients in these categories, considering the patient’s cumulative risk factors and patient preference in making the final decision.

- For nonpregnant patients age 20–39:
  - If lifetime ASCVD risk is 30% to 40%, consider a low-intensity statin.
  - If lifetime ASCVD risk is > 40%, consider a moderate-intensity statin.
- For patients > 75, consider a moderate-intensity statin.

ADDITIONAL TREATMENT

Ezetimibe (Zetia) reduces the amount of cholesterol that is absorbed by the body. It is recommended as second-line treatment for patients who have difficulty achieving control with a statin alone, cannot take statins due to allergy or intolerance, or have ASCVD with certain comorbidities (diabetes, ASCVD event in the last 12 months, or chronic kidney disease).

A PCSK9 inhibitor could be considered as a second- or third-line agent for patients with clinical ASCVD or with a baseline LDL > 190. Providers should review the patient’s insurance coverage before prescribing a PCSK9.

Managing lipid levels

The NLA, AACE, and the 2017 ACC Expert Consensus Document (as well as certain experts at Intermountain) acknowledge there may be a role for treating to lipid levels, especially in certain high-risk patients, such as those with ASCVD. In these circumstances, consider the following LDL guidelines:

- Primary prevention: LDL < 100 mg/dL (especially in diabetics)
- Secondary prevention: ASCVD or baseline LDL < 70 mg/dL, non-HDL < 100 mg/dL

Intermountain also recommends treating triglycerides if they are over 500 mg/dL to reduce the risk of pancreatitis. There is uncertain evidence of cardiovascular risk reduction from this treatment.

Medications. Other classes of lipid-lowering medications include:

- **Fibrates:**
  - Gemfibrozil. Do not initiate in patients who are already on statin therapy because of an increased risk for muscle symptoms and rhabdomyolysis.
  - Fenofibrates. To prevent pancreatitis, consider prescribing concurrently with a low- or moderate-intensity statin only if the benefits are judged to outweigh the risks and primarily when triglycerides remain > 500 mg/dL.

- **Bile acid sequestrants:** Consider using colesevelam for statin-intolerant patients.

- **Omega-3 fatty acids** (fish oil supplements): May be used to lower triglycerides below 500 mg/dL to reduce risk of pancreatitis. Not recommended for reducing the risk of ASCVD.

- **Niacin:** Not recommended

Monitoring. It may be appropriate to perform the following testing to aid in monitoring treatment or compliance:

- **Lipid panel:**
  - At baseline and 4 to 12 weeks after treatment initiation or dose adjustment
  - Annually thereafter

- **Liver function testing:** As a baseline prior to initiating treatment and as clinically indicated thereafter

DOCUMENTING STATIN INTOLERANCE IN iCENTRA

For patients who cannot take a statin due to intolerance (not allergy), the proper way to document this is to add one of the following diagnoses to the problem list (not allergy list):

- G72.0 Drug-induced myopathy
- G72.2 Myopathy due to other toxic agents
- G72.9 Myopathy unspecified
- M62.82 Rhabdomyolysis
- M79.1 Myalgia
- Z78.9 Statin Intolerance

Treatment fundamentals for patients with clinical ASCVD

<table>
<thead>
<tr>
<th></th>
<th>A</th>
<th>B</th>
<th>C</th>
<th>D</th>
<th>E</th>
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<tbody>
<tr>
<td></td>
<td>Aspirin/antiplatelet therapy</td>
<td>Blood pressure control</td>
<td>Cholesterol control and Cigarette smoking cessation</td>
<td>Diet and weight management AND Diabetes and blood glucose control</td>
<td>Exercise</td>
</tr>
</tbody>
</table>
HEART-HEALTHY LIFESTYLE MANAGEMENT

Lifestyle modification is the foundation for ASCVD risk-reduction efforts

Lifestyle modification is a critical component of health promotion and ASCVD risk reduction — both prior to and in conjunction with the use of cholesterol-lowering drug therapies. The recommendations below combine ACC/AHA Guidelines of Lifestyle Management to Reduce Cardiovascular Risk and the AHA Diet and Lifestyle Recommendations.  

<table>
<thead>
<tr>
<th>Lifestyle modification</th>
<th>Recommendation</th>
<th>Notes</th>
</tr>
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</table>
| Adhere to a heart-healthy eating pattern | **Advise all patients to consume a diet that:**  
  • Is rich in vegetables, fruits, and whole grains  
  • Includes low-fat dairy products, poultry, fish, legumes, nontropical vegetable oils, and nuts  
  • Limits sweets, sugar-sweetened beverages, and red meats  
  **Advise adults who would benefit from LDL-C lowering to:**  
  • Consume < 6% of daily calories from saturated fat.  
  • Reduce percent of calories from trans fat to 1% or less.  
  **Advise adults who would benefit from BP lowering to:**  
  • Consume ≤ 2,400 mg of sodium / day.  
  • Further reduce sodium intake to ≤ 1,500 mg / day (associated with even greater reduction in SBP)  
  Note that even when desired daily sodium intake is not achieved, a reduction of 1,000 mg / day from baseline provides some benefit.  
  | Achieve this pattern by following plans, such as the DASH or Mediterranean diet.  
  Adapt dietary pattern to appropriate calorie requirements, personal and cultural food preferences, and nutrition therapy for other conditions, including diabetes. |
| Increase physical activity | **Advise all patients to** engage in regular aerobic physical activity, such as brisk walking, at least 150 minutes / week (30 minutes / day, most days of the week).  
  | This recommendation is consistent with Intermountain’s Lifestyle and Weight Management CPM. |
| Quit tobacco | Complete tobacco cessation. |
| Maintain a normal weight | Weight loss and maintenance are critical for prevention and control of CVD risk factors. |
| Limit alcohol consumption | Limit alcohol to ≤ 2 drinks / day in most men (≤ 1 drink / day if 65 or older), or ≤ 1 drink / day in women and lighter-weight persons. One drink = 12 oz beer, 5 oz wine, or 1.5 oz liquor / hard alcohol. |
RESOURCES

Provider tools

Care Process Models
To find this CPM and all other supporting CPMs, go to intermountainphysician.org/clinicalprograms (see below). Select the Cardiovascular Clinical Program from the list at left and then the topic from the A to Z list at bottom.

Flash Cards
Access related Best Practice Flash Cards by clicking the link below.

Evaluation tools
The Intermountain Primary Care Clinical Program maintains a database of patients with certain risk factors who should be on a statin (HEDIS and STARS measures). The purpose of the database is to improve clinical care.

The Diabetes Statin Report and the ASCVD Statin Report assess the percentage of patients with these conditions who are on a statin. Using this information, providers can identify patients who aren't on a statin but could potentially benefit from being on a statin.

Throughout this CPM, the icon indicates instances where data is collected about these patient cohorts. Reports are updated monthly and are available to Intermountain-employed providers through the Reports Center. Affiliated providers receive their reports through SelectHealth. If you have questions about your report, please contact Stephen Smith at Stephen_C_Smith@imail.org.
RESOURCES (CONTINUED)

Patient education

Access to patient materials

Intermountain education materials are designed to support your efforts to educate and engage patients and families. They complement and reinforce cholesterol management team interventions by providing a means for patients to reflect and learn in another mode and at their own pace. To access these materials:

- **As the iCentra EMR system is implemented**, search for Intermountain items in the patient education module.

- **Log in to Intermountainphysician.org**, and search for the patient education library under A–Z. Then, search the item number and title in the appropriate area.

- **Use Intermountain’s Online Education Library and Print Store** for one-stop access and ordering for all Intermountain-approved education, such as fact sheets, booklets, and trackers.

Suggested patient education

Fact sheets:
- **Understanding Cholesterol**
- **Cholesterol: Statin Medication Decision Guide**
- **Statins**
- **High Blood Pressure and the DASH Diet**
- **Mediterranean Diet**
- **Live Well, Move More**

Other patient education:
- **Quitting Tobacco**
- **Heart Care Handbook**
This CPM presents a model of best care based on the best available scientific evidence at the time of publication. It is not a prescription for every physician or every patient, nor does it replace clinical judgment. All statements, protocols, and recommendations herein are viewed as transitory and iterative. Although physicians are encouraged to follow the CPM to help focus on and measure quality, deviations are a means for discovering improvements in patient care and expanding the knowledge base. Send feedback to Mark R. Greenwood, Medical Director, Primary Care Clinical Program, MarkR.Greenwood@imail.org.