



Guidelines for Lipid Screening and Management

For the complete guideline, please go to:

<http://www.acc.org/tools-and-practice-support/expert-consensus-decision-pathways>

Or

<http://www.onlinejacc.org/content/early/2017/08/30/j.jacc.2017.07.745>

Guideline History

Original Approved Date	Adult: 06/01 Pediatric: 10/05
Review/Revised Dates	10/03, 10/05, 10/07, 11/09, 01/10, 05/10, 5/12, 05/14, 07/16, 5/18
Next Review Date	05/20

These clinical guidelines are issued by Sentara Health Plan (SHP) as recommendations for the clinical management of specific conditions. Clinical data in a particular case may necessitate for permit deviation from these Guidelines. The SHP Guidelines are institutionally endorsed recommendations and are not intended as a substitute for clinical judgment.

Key Reference Points

Algorithms

- **Figure 2B: Algorithm** Patients ≥ 21 Years of Age with Clinical ASCVD with Comorbidities, on Statin for Secondary Prevention.
 - Patients with clinical ASCVD and comorbidities should be treated first with maximally tolerated statin intensity.

- **Figure 2C: Algorithm** Patients ≥ 21 Years of Age with Clinical ASCVD and Baseline LDL-C ≥ 190 mg/dl Not Due to Secondary Causes, On Statin for Secondary Prevention.
 - Patients with ASCVD and primary, severe elevations of LDL-C ≥ 190 mg/dL are at very high risk for future ASCVD events because of their lifetime exposure to markedly elevated LDL-C levels. This risk is accelerated in the presence of other ASCVD risk factors

- **Figure 3: Algorithm** Patients ≥ 21 Years of Age without Clinical ASCVD and with a Baseline LDL-C ≥ 190 mg/dl Not Due to Secondary Causes, on Statin for Primary Prevention.
 - Patients with baseline elevation of LDL-C ≥ 190 mg/dL not due to secondary modifiable causes are at very high risk of first and recurrent ASCVD events because of their lifetime exposure to markedly elevated LDL-C levels, and therefore, 10-year ASCVD risk assessment is not indicated in this high-risk population.

- **Figure 4: Algorithm** Patients Aged 40-75 Years without Clinical ASCVD and with Diabetes and Baseline LDL-C 70-189mg/dl, on Statin for Primary Prevention.
 - Patients with diabetes are at higher risk for ASCVD events due to diabetes itself and also to the concomitant burden of other cardio metabolic risk factors that tend to cluster in patients with type 1 or type 2 diabetes.

- **Figure 5: Algorithm** Patients Aged 40-75 Years without Clinical ASCVD or Diabetes, with LDL-C 70-189mg/dl and 10 Year ASCVD Risk $\geq 7.5\%$, on Statin for Primary Prevention.
 - Based on a high level of evidence, the guideline recommended that these patients be considered for treatment with moderate- to high-intensity statin. Younger patients without ASCVD but with ASCVD risk factors typically have low 10-year predicted risks for ASCVD but high lifetime predicted risks.

Tables

- **Table 3:** Examples of High, Moderate, and Low Intensity Statin Therapy (Adapted from 2013 ACC/AHA Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults).
 - Clinicians treating high-risk patients who have a less-than-anticipated response to statins, who are unable to tolerate a less-than-recommended intensity of a statin, or who are completely statin intolerant, may consider the addition of a non-statin cholesterol-lowering therapy. High-risk individuals include those with ASCVD, those with LDL-C ≥ 190 mg/dL, and those with diabetes 40 to 75 years of age.

- **Table 4:** Strategies and Non-Statin Agents Considered for Management of LDL-Related ASCVD Risk
 - Table 4 outlines the important considerations in the choice of non-statin pharmacological agents that may make a treatment modality preferable in specific patient populations (e.g., pregnant women, elderly patients, patients with diabetes).

- **Table 5:** Factors to Consider in the Clinician Patient Discussion
 - Before initiation of combination therapy, it is imperative for clinicians and patients to engage in a discussion that addresses the potential for net benefit, including absolute ASCVD risk-reduction benefits and potential harms, prescribing considerations, and patient preferences for treatment.

Attachments

- **Attachment 1:** 2017 Recommendation of the National Lipid Association (NLA) Expert Panel on Treatment with PCSK9 Inhibitors.

NLA Expert Panel on Treatment with PCSK9 Inhibitors

An Expert Panel convened by the National Lipid Association (NLA) was charged with updating the recommendations on the use of proprotein convertase subtilisin/kexin type 9 (PCSK9) inhibitor therapy that were provided by the 2015 NLA Recommendations for the Patient-Centered Management of Dyslipidemia: Part 2.



Atherosclerotic Cardiovascular Disease (ASCVD)

1. PCSK9 inhibitor therapy should be considered for ASCVD risk reduction in patients with **stable ASCVD**, particularly in those with additional ASCVD risk factors, on maximal-tolerated statin therapy ± ezetimibe, with on-treatment LDL-C ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL. Strength: A, Quality: High.
2. PCSK9 inhibitor therapy may be considered to further reduce LDL-C in patients with **progressive ASCVD** on maximal tolerated statin therapy ± ezetimibe, and on-treatment LDL-C ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL. Strength: B, Quality: Moderate.



Very High Risk/Statin Intolerance

4. PCSK9 inhibitor therapy may be considered to further reduce LDL-C in selected very high-risk patients who meet the definition of statin intolerance (as previously defined by the NLA Statin Expert Panel)** and who require substantial additional atherogenic cholesterol lowering, despite the use of other lipid lowering therapies. Strength: C, Quality: Low.



FH Phenotype/ LDL-C \geq 190 mg/dL

- 3a. PCSK9 inhibitor therapy may be considered to further reduce LDL-C in **patients age 40-79 years** with pre-treatment LDL-C ≥ 190 mg/dL, **no uncontrolled ASCVD risk factors** or other key additional high risk markers*, and on-treatment LDL-C ≥ 100 mg/dL or non-HDL-C ≥ 130 mg/dL on maximal-tolerated statin therapy ± ezetimibe. Strength: B, Quality: Moderate.
- 3b. PCSK9 inhibitor therapy may be considered to further reduce LDL-C in **patients age 40-79 years** with pre-treatment LDL-C ≥ 190 mg/dL and the presence of **uncontrolled ASCVD risk factors**, key additional high risk markers*, or genetic confirmation of FH, and on-treatment LDL-C ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL on maximal-tolerated statin ± ezetimibe. Strength: B, Quality: Moderate.
- 3c. PCSK9 inhibitor therapy may be considered to further reduce LDL-C in **patients age 18-39 years** with FH phenotype/ pre-treatment LDL-C ≥ 190 mg/dL and the presence of either **uncontrolled ASCVD risk factors**, key additional high risk markers*, or genetic confirmation of FH, and on-treatment LDL-C ≥ 100 mg/dL or non-HDL-C ≥ 130 mg/dL on maximal-tolerated statin ± ezetimibe. Strength: E, Quality: Low.
- 3d. PCSK9 inhibitor therapy may be considered to further reduce LDL-C in patients with **homozygous FH**, either of unknown genotype, or those known to be LDL receptor defective, on maximal-tolerated statin therapy ± ezetimibe with LDL-C ≥ 70 mg/dL or non-HDL-C ≥ 100 mg/dL. Strength: B, Quality: Moderate.

*Including history of uncontrolled high blood pressure, diabetes, current cigarette smoking or family history of premature ASCVD; or additional high risk markers (coronary calcium ≥ 300 Agatston units [or ≥ 75 th percentile for the patient's age, gender and ethnicity]; Lp(a) ≥ 50 mg/dL using an isoform insensitive assay, hs-CRP ≥ 2 mg/L or CKD including albumin/creatinine ratio ≥ 30 mg/g).

**Such as those who had previous ASCVD events in the presence of additional risk factors.