

SCAN Health Plan® 5-Star Webinar Series

# Statins in Action

*Use, Opportunities, and Benefits*

Sept. 26, 2019



SCAN Health Plan confidential and proprietary information. © 2019 SCAN Health Plan. All rights reserved.



# Disclosure Statement

---

This activity has received no commercial support.

None of the faculty or planners have any relevant financial relationships with commercial interest to disclose.

- John (Chris) Champion, MD, Cardiologist, Pacific Cardiovascular Associates      Presenter
- Kelly Chen, PharmD, Clinical Pharmacist, SCAN Health Plan      Planner
- Terence Offenberger, MD, MBA, VP CA Medical Director, SCAN Health Plan      Facilitator
- Sarah Pham, MHA, Network Quality Specialist, SCAN Health Plan      Planner
- Tracy Valenzuela, MBA, 5-Star Project Manager, SCAN Health Plan      Planner

# Accreditation Statement

---

## Physicians

SCAN Health Plan (SCAN) is accredited by the Institute of Medical Quality/California Medical Association (IMQ/CMA) to provide continuing medical education for physicians. SCAN designates this live activity for **a maximum of 1 AMAPRA Category 1 Credit™**. Physicians should claim only the credit commensurate with the extent of their participation in the activity. This credit may also be applied to the CMA certification in Continuing Medical Education.

## Nurses

SCAN is approved as a provider (#CEP-13453) by the California Board of Registered Nursing. This activity has been approved for **up to one contact hour**.

## Pharmacists

Coursework which meets the standards of relevance to pharmacy practice and has been approved for continuing education by the California Board of Registered Nursing, upon satisfactory completion, be considered continuing education for pharmacists. (CCR 1372.2(b))

This activity has been approved for up to 1 contact hour. All pharmacists shall retain their certificates of completion for four (4) years following completion of a continuing education course. (CCR 1372.5(c))

*SCAN maintains responsibility for this program/course and its content.*

# We Need Your Help!

- ▶ Statin therapy use for the prevention of atherosclerotic cardiovascular disease (ASCVD) is supported by extensive evidence!
- ▶ Yet, statin treatment rates have remained unchanged since 2013 for patients with ASCVD and for patients with diabetes.

Statin therapy is crucial for primary and secondary prevention of heart attacks and strokes.

# 2019 Statin Therapy Measures

## SUPD

### **Statin Use in Persons with Diabetes (SUPD)**

Diabetic patients between 40-75 who filled a statin

Primary prevention of cardiovascular events

## SPC

### **Statin Therapy for Patients with Cardiovascular Disease (SPC)**

Males 21-75 and females 40-75 who have clinical ASCVD and were dispensed one *moderate- or high-* dose statin

Secondary prevention of cardiovascular events

# CMS Technical Specifications

## Inclusion Criteria

**SUPD:** patients with diabetes is defined by those who have at least 2 fills of diabetes medication during the measurement year

**SPC:** patients identified as having clinical atherosclerotic cardiovascular disease (ASCVD)

## Exclusion Criteria

**SPC only:** *Myalgia*, myositis, myopathy, or rhabdomyolysis such as:

- M79.1 – Myalgia
- M79.10 – Myalgia, unspecified site
- G72.0 – Drug induced myopathy

**SUPD and SPC:** ESRD and hospice

# 2019 5-Star Statin Measure Performance

SPC Measure



SUPD Measure



ADH \_ Statin Measure



We understand the barriers you face in prescribing statins. Dr. Champion will discuss the strategies that you can use to better communicate with your patients on the importance of statin therapy.

\*SCAN Data as of 8/13/2019

SCAN Health Plan confidential and proprietary information. © 2019 SCAN Health Plan. All rights reserved.



# Learning Objectives

At the conclusion of this activity, participants will be able to:

- ▶ Describe the mechanism of action of the statin drug class that improves cardiovascular outcomes.
- ▶ Discuss the updated prescribing guidelines of statin therapy for high-risk populations (including patients with diabetes and cardiovascular disease) in order to formulate a cholesterol treatment plan.
- ▶ Evaluate the risk and benefits of statin therapy for special patient cases (e.g., statin intolerance, etc.) using scientific literature.



# John (Chris) Champion, MD

Cardiologist, Pacific Cardiovascular Associates

- Doctor of Medicine degree at the University of Texas Medical Branch (UTMB) in Galveston
- Completed his internal medicine residency as well as his cardiology fellowship
- Served as assistant professor of medicine in heart failure and transplant while at UTMB
- Aided in the development of the cardio-oncology program at the Texas Medical Center in Houston
- Board certified in internal medicine and cardiovascular disease
- Expert at non-invasive cardiology and has special proficiency and advanced expertise in the management of complex congestive heart failure patients



# Statins in Action

Presented by:  
**Chris Champion, MD**  
Cardiology  
Pacific Cardiovascular Associates



Collaborative Educational Webinar

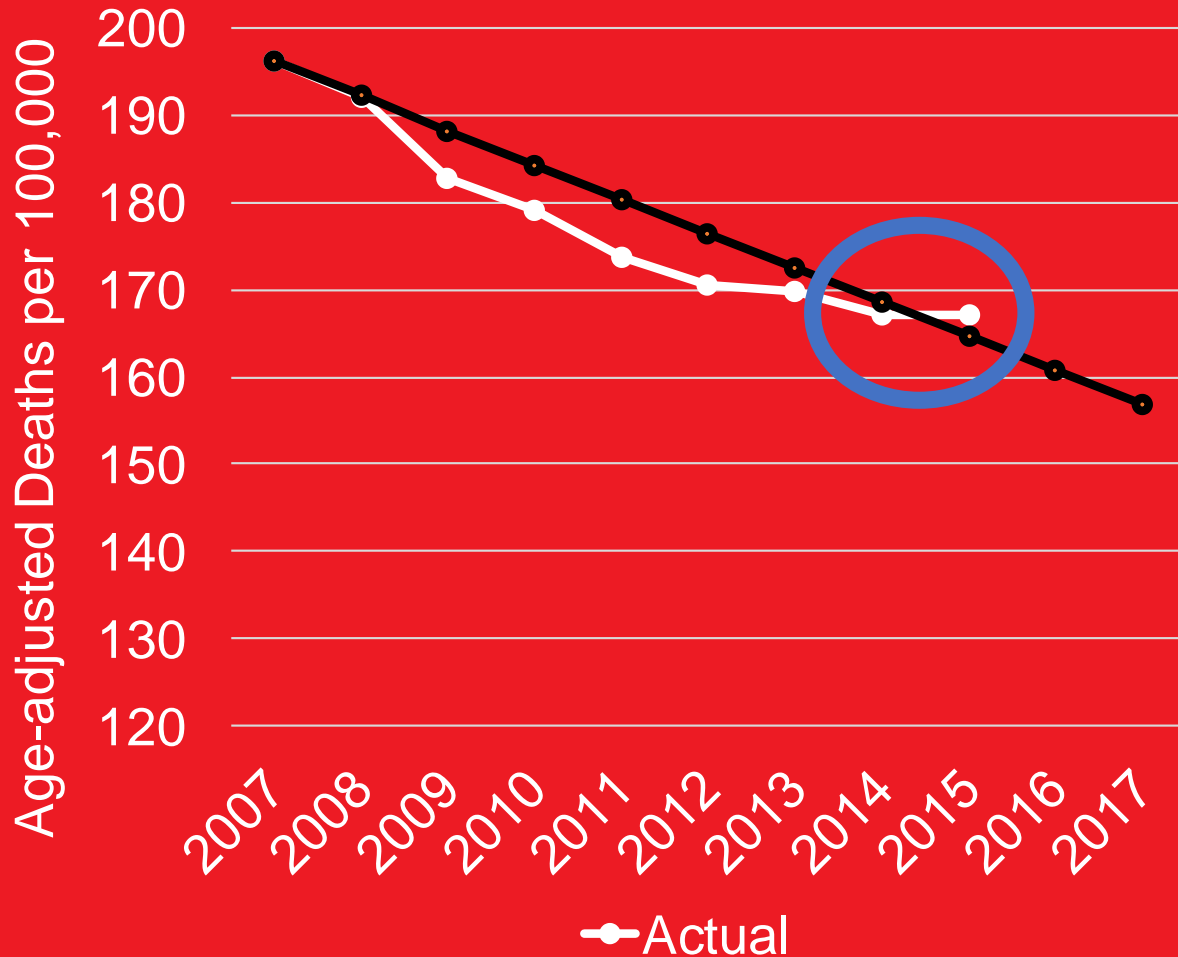
# Overview

Cardiovascular disease continues to be the number one cause of death in the US. According to the American Heart Association and American Stroke Association 2017 Heart Disease and Stroke Statistical report:

- About **92.1 million** adults currently are living with heart disease or have suffered a stroke.
- Cardiovascular disease accounts for almost **801,000 deaths** in the U.S. each year and is still the leading cause of death globally.
- Coronary heart disease accounts for **1 in 7 deaths** and stroke accounts for **1 in 20 deaths** here in the U.S.
- It is estimated that **790,000** Americans have a heart attack each year and **795,000** have a new or recurrent stroke.

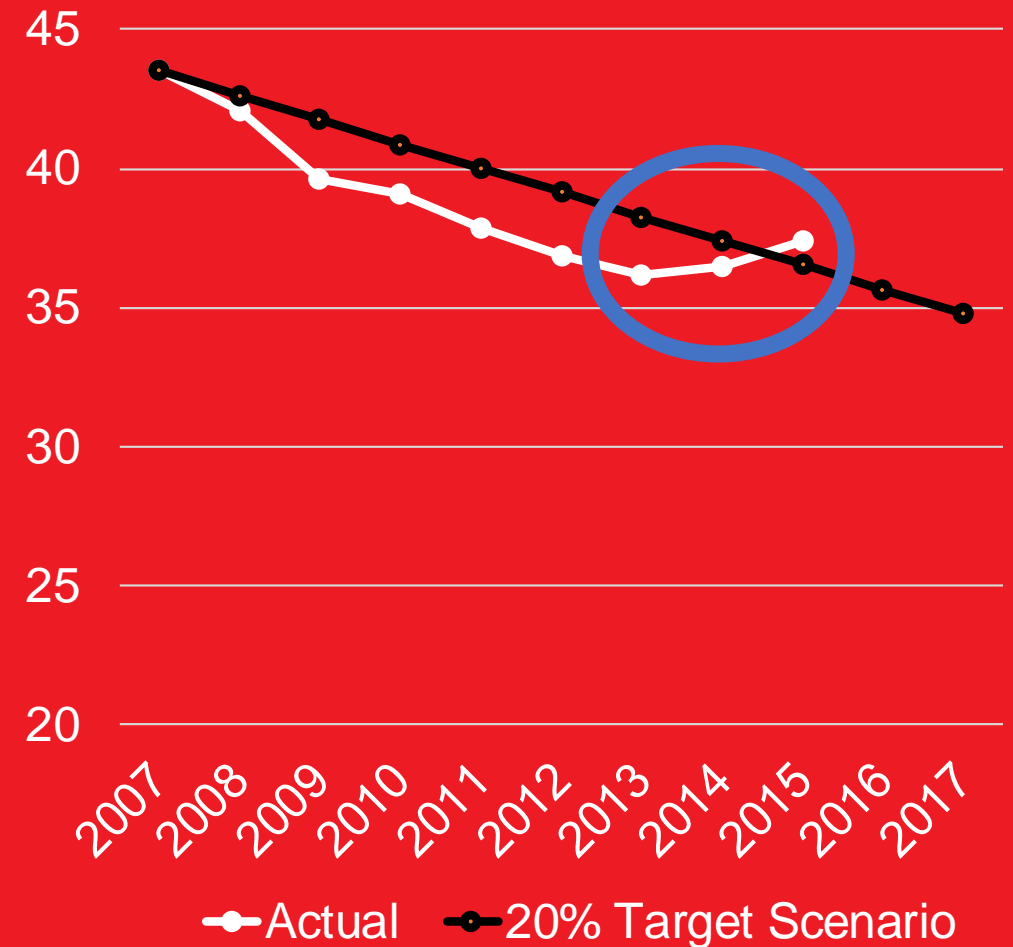
# MORE PEOPLE ARE DYING FROM HEART DISEASE AND STROKE

## HEART DISEASE



Source: NVSS 2007-2015. Heart Disease: I00-I09, I11, I13, and I20-I51

## STROKE



Source: NVSS 2007-2015. Stroke: I60-I69

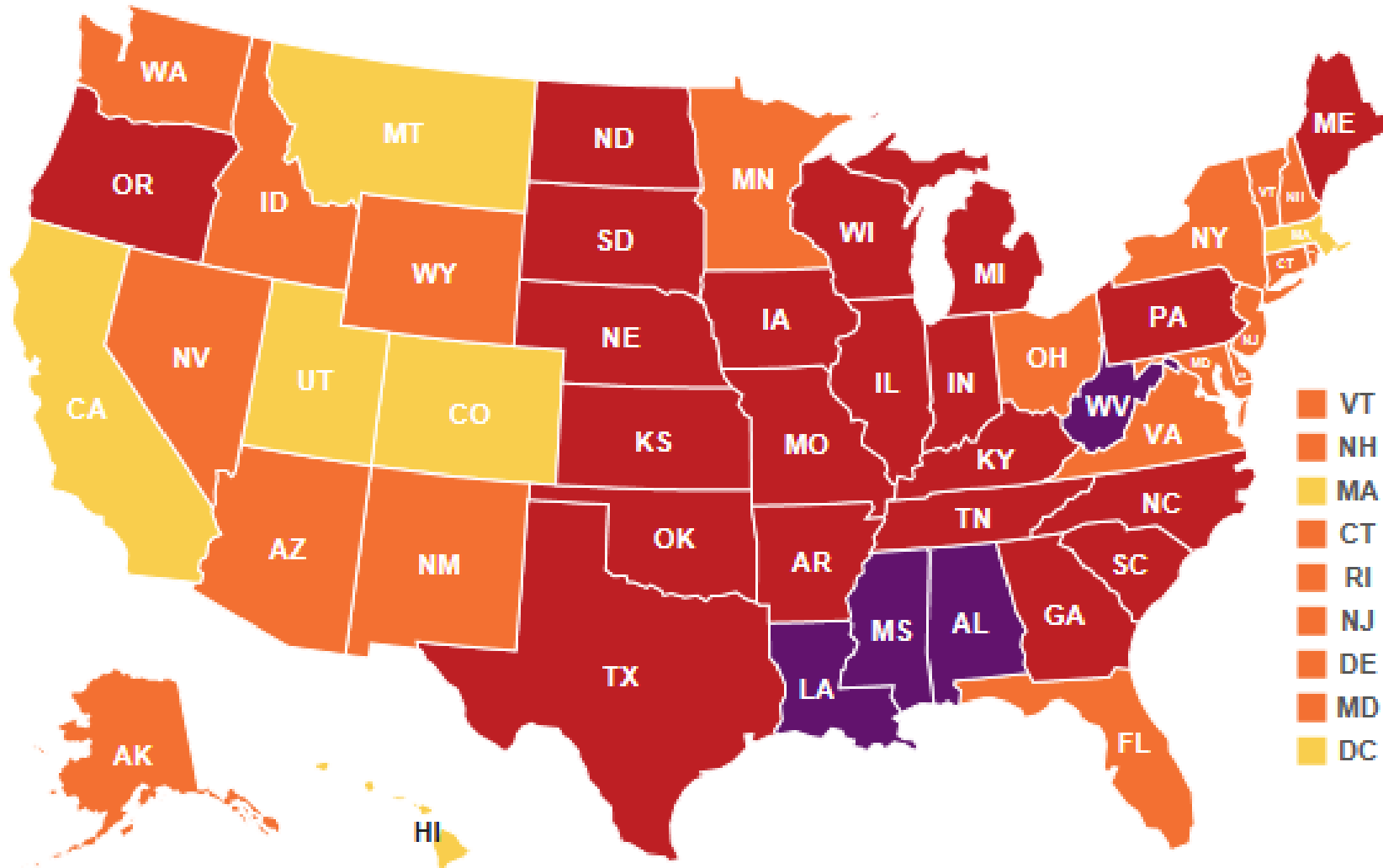


# PERCENT OF OBESE ADULTS BY STATE

(Body Mass Index of 30+)

0 - 9.9%   10 - 14.9%   15 - 19.9%   20 - 24.9%   25 - 29.9%   30 - 34.9%   35%+

2015



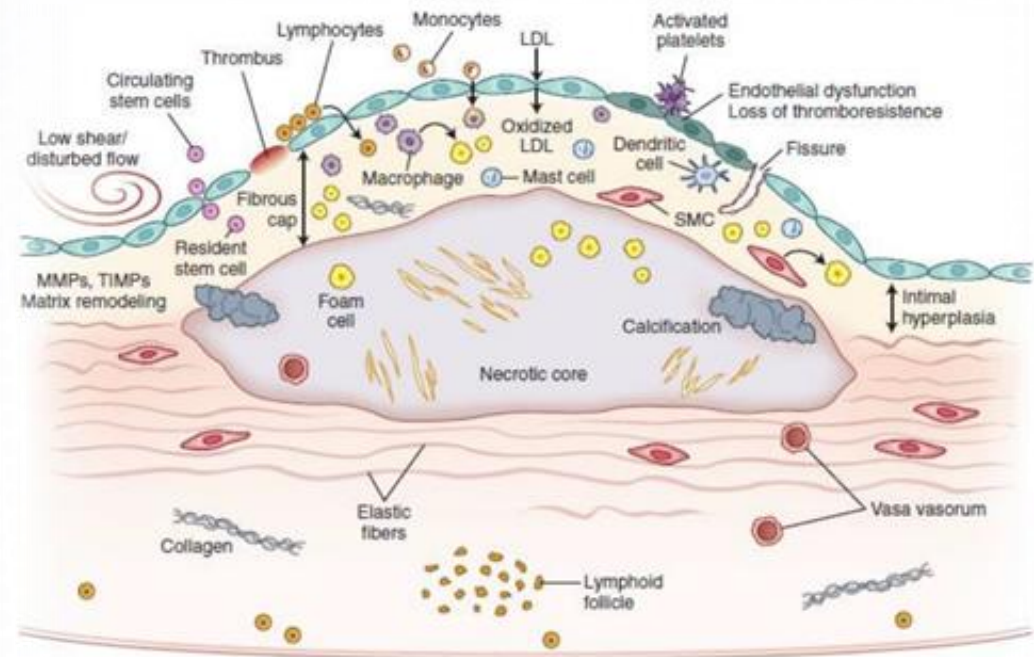
## High Cholesterol is an Important Risk Factor

- High cholesterol is a major risk factor for cardiovascular disease and stroke (No. 1 & No. 5 causes of death in the U.S.)
- The incidence of ASCVD events increases dramatically with each decade of life after 45 years of age **in all sex and racial/ethnic groups**
- Despite several effective strategies for primary prevention of ASCVD, these **strategies are frequently underused and some high-risk patients are often undertreated**

ASCVD = atherosclerotic cardiovascular disease

# Atherosclerosis

- A disease of the vascular intima characterized by fatty deposits called atheromatous plaques that occlude into the vessel lumen
- Consequences:
  - Local Effects:
    - Vessel occlusion/stenosis
    - Thrombosis
  - Ischemic Heart Disease
    - Coronary Artery Disease
    - Angina
    - Myocardial Infarctions
  - Cerebral Vascular Disease
    - Ischemic or hemorrhagic stroke
  - Peripheral Vascular Disease
    - Peripheral Artery Disease

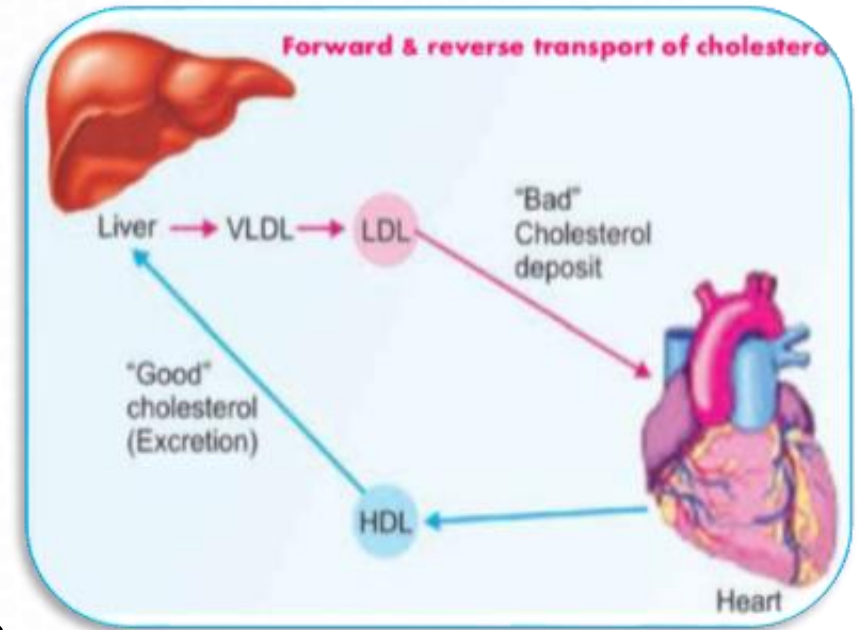


Advanced atherosclerotic plaque in aorta

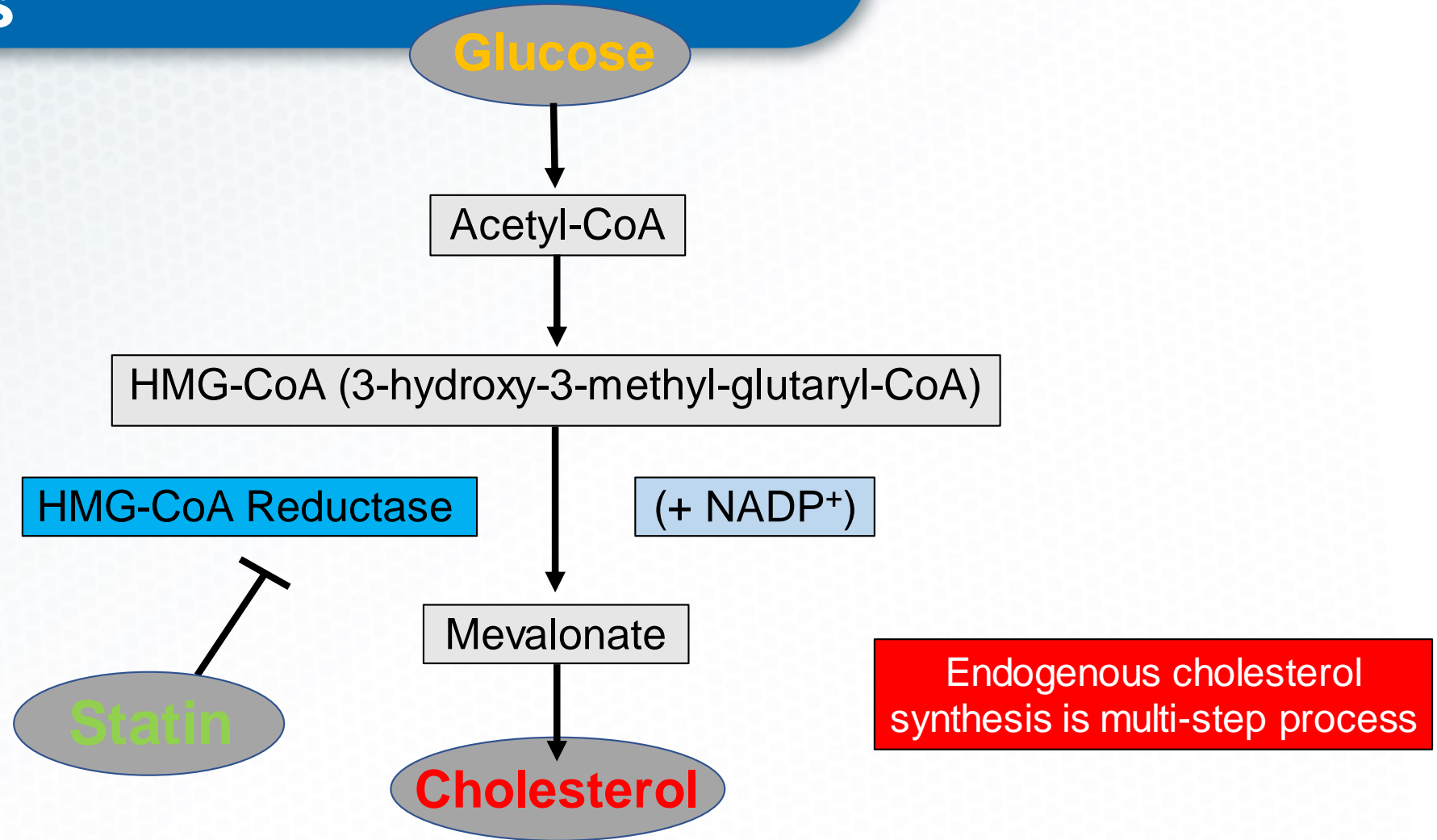


# Cholesterol

- Lipoproteins normally function to transport cholesterol from its site of synthesis (liver) to other tissues of body
  - Chylomicrons
  - Very-low-density lipoproteins (VLDL)
  - Intermediate-density lipoproteins (IDL)
  - Low-density lipoproteins (LDL) – “bad”
  - High-density lipoproteins (HDL) – “good”
- The pathogenesis of atherosclerosis involves uptake of oxidized-LDL by macrophages and smooth muscle cells
  - Lower LDL-c levels may inhibit atherosclerosis



# Cholesterol Synthesis and Statins



# Effect of Statins

- Statins lower cholesterol levels:
  - **Directly** – cholesterol synthesis is inhibited via inhibition of HMG-CoA reductase
  - **Indirectly** – decreased cellular cholesterol due to the direct effects of statins causes increased uptake of circulating cholesterol from the vasculature.
- Net effect: Reduced circulating LDL cholesterol and suppression of atherogenesis

# Cholesterol Guidelines

## 2018 Guideline on the Management of Blood Cholesterol

Joint Expert Panel

AHA/ACC/AACVPR/AAPA/ABC/ACPM/ADA/AGS/APhA/ASPC/NLA/PCNA

Updated Article Published in: *Journal of the American College of Cardiology*. Jun 2019, 73 (24) e285-e350; DOI: 10.1016/j.jacc.2018.11.003

The full-text guidelines are also available on the following Web sites: ACC ([www.acc.org](http://www.acc.org)) and AHA ([professional.heart.org](http://professional.heart.org))

# Use of ASCVD Risk Assessment in Cholesterol Guidelines

- Previous cholesterol guidelines emphasized the use of statin therapy to treat to target cholesterol levels.
- The current ACC/AHA guidelines focus instead on the use of statin therapy to address the broader goal of reducing ASCVD risk and events.
- Now, guideline recommendations include the use of statin therapy as first-line treatment **not only** for high cholesterol patients **but also** for certain patients with known ASCVD or those with elevated risk for ASCVD.
- Before initiating statin treatment in any patient, it should be emphasized that lifestyle changes are still critical to ASCVD prevention and cholesterol management.

# Cholesterol Guidelines

The 2018 Cholesterol Treatment Guidelines identify those who will be the **most likely to benefit from statin use**:

- Adults with known ASCVD
- Adults with diabetes mellitus, aged 40-79 years with an LDL-C level > 70 mg/dL
- Adults with LDL-C level of > 190 mg/dL
- Adults with LDL-C level of 70-189 mg/dL and **7.5% or greater 10 year risk of developing ASCVD** (without clinical ASCVD or DM)

# ASCVD Risk Assessment Calculator for Primary Prevention

Utilizes various factors to assess patients who have not had a prior ASCVD event and assigns a 10-year risk score. Patients are considered to be at elevated risk if the 10-year risk score is  $\geq 7.5\%$ .

## When to USE the calculator:

- Patients 40 to 79 years of age (without established ASCVD)
- Patients with LDL levels 70 to 189 mg/dL without ASCVD and not already on statin therapy

## When NOT to use the calculator:

- NOT for patients <40 years of age or >79 years of age
- NOT for patients with established ASCVD or with symptoms suggestive of CVD
- NOT for patients on hemodialysis
- NOT for subgroups of high-risk patients, such as those with severe or familial hypercholesterolemia



<http://tools.acc.org/ASCVD-Risk-Estimator-Plus>

tools.acc.org/ASCVD-Risk-Estimator-Plus/#/calculate/estimate/

Practice Fusion Hoag Hospital Oran... ASCVD Risk Estimat... ACS NSQIP Risk Cal... Online STS Risk Cal... Insuperity Portal | Lo... eTenet I MemorialCare Link KPC Health ARMC

### ASCVD Risk Estimator Plus

[Estimate Risk](#)

App should be used for primary prevention patients (those without ASCVD) only.

**Current Age** \*  Age must be between 20-79

**Sex** \*  Male  Female

**Race** \*  White  African American  Other

**Systolic Blood Pressure (mm Hg)** \*  Value must be between 90-200

**Diastolic Blood Pressure (mm Hg)** °  Value must be between 60-130

**Total Cholesterol (mg/dL)** \*  Value must be between 130 - 320

**HDL Cholesterol (mg/dL)** \*  Value must be between 20 - 100

**LDL Cholesterol (mg/dL)** °  Value must be between 30-300

**History of Diabetes?** \*  Yes  No

**Smoker?** \*  Current °  Former °  Never °

**On Hypertension Treatment?** \*  Yes  No

**On a Statin?** °  Yes  No

**On Aspirin Therapy?** °  Yes  No

**Do you want to refine current risk estimation using data from a previous visit?** °  Yes  No

[Determine Therapy Impact](#)

[View Advice](#)

Gender	Race
Blood Pressure	Diabetes
Total Cholesterol	Hypertension Treatment
HDL Cholesterol	Smoking Status

# ASCVD PLUS: An App for that too...

AT&T 1:19 AM 32%

10-Year ASCVD Risk	Lifetime ASCVD Risk
20.9% <small>calculated risk</small>	69% <small>calculated risk</small>
5.2% <small>risk with optimal risk factors**</small>	5% <small>risk with optimal risk factors</small>

Recommendation Based On Calculation

Other

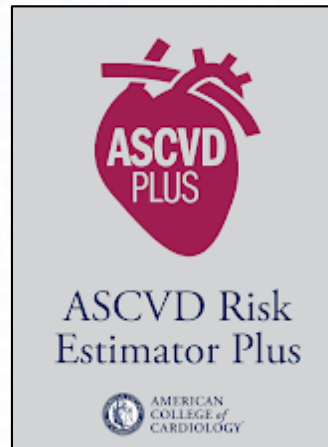
Total Cholesterol (mg/dL)

HDL - Cholesterol (mg/dL)

Systolic Blood Pressure

Treatment for Hypertension  Y  N

Diabetes  Y  N



Phone

iPad 9:27 AM 35%

Estimator Clinicians Patients About

ASCVD Risk Estimator\*

10-Year ASCVD Risk	Lifetime ASCVD Risk
6.2% <small>calculated risk</small>	50% <small>calculated risk</small>
5.2% <small>risk with optimal risk factors**</small>	5% <small>risk with optimal risk factors</small>

Recommendation Based On Calculation

Gender  Male  Female

Age

Total Cholesterol (mg/dL)

Race  White  African American  Other

HDL - Cholesterol (mg/dL)

Systolic Blood Pressure

Treatment for Hypertension  Yes  No

Diabetes  Yes  No

Smoker  Yes  No

\*Intended for use if there is not ASCVD and the LDL-cholesterol is <190 mg/dL  
 \*\*Optimal risk factors include: Total cholesterol of 170 mg/dL, HDL-cholesterol of 50 mg/dL, Systolic BP of 110 mm Hg, Not taking medications for hypertension, Not a diabetic, Not a smoker

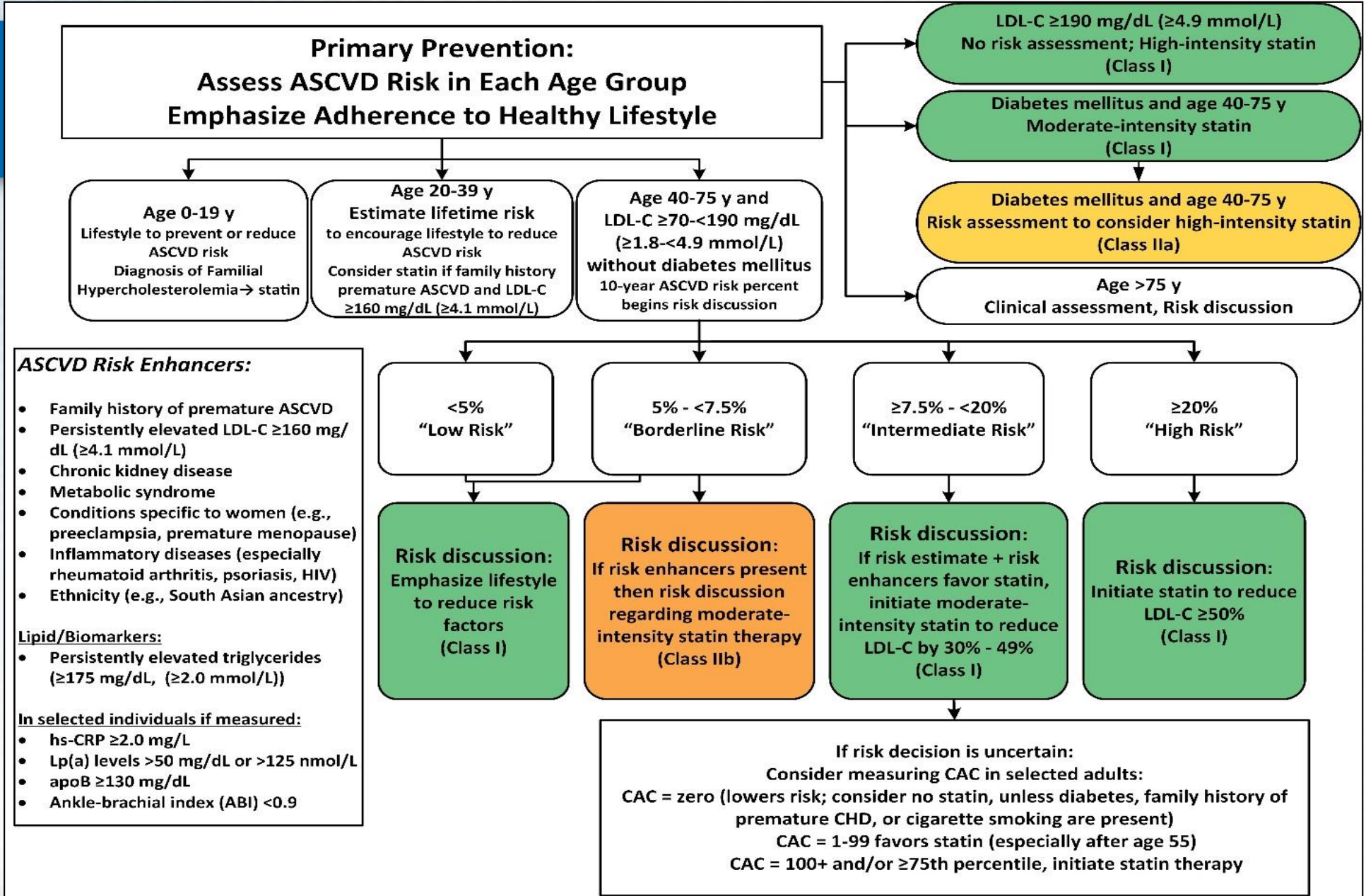
AMERICAN COLLEGE OF CARDIOLOGY | American Heart Association  
 Published jointly by ACC and AHA | © 2014

Tablet

## Adults with Known ASCVD: Secondary Prevention

**In patients with clinical ASCVD, reduce low-density lipoprotein cholesterol (LDL-C) with high-intensity statin therapy or maximally tolerated statin therapy.**

- The more LDL-C is reduced on statin therapy, the greater will be subsequent risk reduction.
- Use a maximally tolerated statin to lower LDL-C levels by  $\geq 50\%$ .



# Adults with Diabetes Mellitus

In patients **40 to 75** years of age **with diabetes mellitus** and **LDL-C  $\geq 70$  mg/dL**, start moderate-intensity statin therapy without calculating 10-year ASCVD risk.

- In patients with diabetes mellitus at higher risk, especially those with multiple risk factors or those 50 to 75 years of age, it is reasonable to use a high-intensity statin to reduce the LDL-C level by  $\geq 50\%$ .

# Adults with Severe Hypercholesterolemia

In patients with **severe primary hypercholesterolemia** (LDL-C level  $\geq 190$  mg/dL) without calculating 10-year ASCVD risk, begin high-intensity statin therapy without calculating 10-year ASCVD risk.

- If the LDL-C level remains  $\geq 100$  mg/dL ( $\geq 2.6$  mmol/L), adding ezetimibe is reasonable
- If the LDL-C level on statin plus ezetimibe remains  $\geq 100$  mg/dL ( $\geq 2.6$  mmol/L) & the patient has multiple factors that increase subsequent risk of ASCVD events, a PCSK9 inhibitor may be considered

# Adults without Diabetes Mellitus

In adults **40 to 75** years of age without diabetes mellitus and with LDL-C levels  **$\geq 70$  mg/dL**, at a 10-year ASCVD risk of  **$\geq 7.5\%$** , start a moderate-intensity statin if a discussion of treatment options favors statin therapy.

- Risk-enhancing factors favor statin therapy (next slide)
- If risk status is uncertain, consider using coronary artery calcium scoring (CAC) to improve specificity
- If statins are indicated, reduce LDL-C levels by  $\geq 30\%$ , and if 10-year risk is  $\geq 20\%$ , reduce LDL-C levels by  $\geq 50\%$

# Risk-Enhancing Factors for Clinician–Patient Risk Discussion

## Risk-Enhancing Factors

- **Family history of premature ASCVD** (males, age <55 y; females, age <65 y)
- **Primary hypercholesterolemia** (LDL-C, 160–189 mg/dL [4.1–4.8 mmol/L]; non-HDL-C 190–219 mg/dL [4.9–5.6 mmol/L])\*
- **Metabolic syndrome** (increased waist circumference, elevated triglycerides [ $>175$  mg/dL], elevated blood pressure, elevated glucose, and low HDL-C [ $<40$  mg/dL in men;  $<50$  in women mg/dL] are factors; tally of 3 makes the diagnosis)
- **Chronic kidney disease** (eGFR 15–59 mL/min/1.73 m<sup>2</sup> with or without albuminuria; not treated with dialysis or kidney transplantation)
- **Chronic inflammatory conditions** such as psoriasis, RA, or HIV/AIDS
- **History of premature menopause (before age 40 y) and history of pregnancy-associated conditions that increase later ASCVD risk such as preeclampsia**
- **High-risk race/ethnicities** (e.g., South Asian ancestry)

\*Risk-enhancing factors may favor statin therapy in patients at 10-year risk of 5-7.5% (borderline risk)



# Risk-Enhancing Factors for Clinician–Patient Risk Discussion

## Risk-Enhancing Factors

- **Lipid/biomarkers:** Associated with increased ASCVD risk
  - Persistently\* elevated, primary hypertriglyceridemia ( $\geq 175$  mg/dL);
  - If measured:
    - **Elevated high-sensitivity C-reactive protein** ( $\geq 2.0$  mg/L)
    - **Elevated Lp(a):** A relative indication for its measurement is family history of premature ASCVD. An Lp(a)  $\geq 50$  mg/dL or  $\geq 125$  nmol/L constitutes a risk-enhancing factor especially at higher levels of Lp(a).
    - **Elevated apoB**  $\geq 130$  mg/dL: A relative indication for its measurement would be triglyceride  $\geq 200$  mg/dL. A level  $\geq 130$  mg/dL corresponds to an LDL-C  $> 160$  mg/dL and constitutes a risk-enhancing factor
    - **ABI**  $< 0.9$

\*Risk-enhancing factors may favor statin therapy in patients at 10-year risk of 5-7.5% (borderline risk)

# Coronary Artery Calcium Score (CAC)

**In adults 40 to 75 years of age without diabetes mellitus and with LDL-C levels  $\geq 70$  mg/dL- 189 mg/dL ( $\geq 1.8$ -4.9 mmol/L), at a 10-year ASCVD risk of  $\geq 7.5\%$  to 19.9%, if a decision about statin therapy is uncertain, consider measuring CAC.**

- If CAC is **zero**, treatment with statin therapy may be withheld or delayed, except in cigarette smokers, those with diabetes mellitus, and those with a strong family history of premature ASCVD.
- A CAC score of **1 to 99** favors statin therapy, especially in those  $\geq 55$  years of age.
- For any patient, if the CAC score is  **$\geq 100$**  Agatston units or  **$\geq 75$ th percentile**, statin therapy is indicated unless otherwise deferred by the outcome of clinician–patient risk discussion.

# Patients Who Might Benefit From Knowing Their CAC Score Is Zero

## CAC Measurement Candidates Who Might Benefit from Knowing Their CAC Score Is Zero

- Patients reluctant to initiate statin therapy who wish to understand their risk and potential for benefit more precisely
- Patients concerned about need to reinstitute statin therapy after discontinuation for statin-associated symptoms
- Older patients (men, 55-80 y of age; women, 60-80 y of age) with low burden of risk factors who question whether they would benefit from statin therapy
- Middle-aged adults (40-55 y of age) with PCE-calculated 10-year risk of ASCVD 5% to <7.5% with factors that increase their ASCVD risk, although they are in a borderline risk group

# Poll #1

---

What are the most common barriers that you experience that prevent patients from taking their statins? (Check all that apply)

- A. I don't have enough time to address it
- B. My patients are resistant to statin therapy
- C. My patients have history of side effect or intolerance to statins
- D. The cholesterol treatment guidelines aren't clear
- E. Other

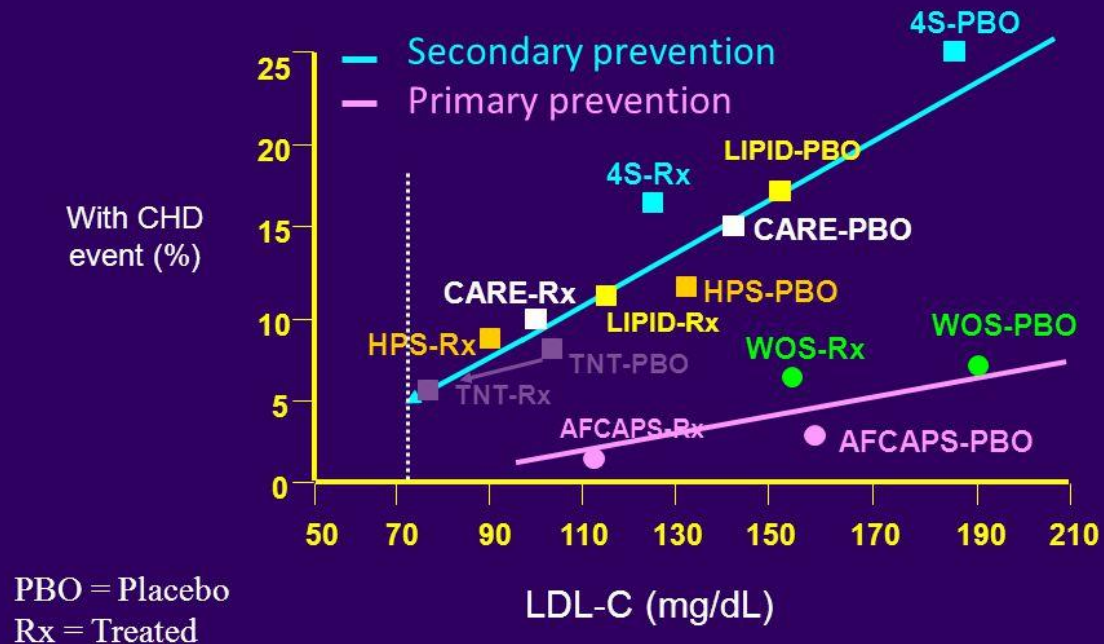
# Statin Dosing

I am never quite certain which agent to use or which dose to initiate.

What is really the proper treatment for patients?

# LDL: Lower is Better

Statin in **primary** and **secondary** prevention trials ;  
*The lower the better*



# Statin Therapy

- Intensity of statin therapy is defined based on the average LDL-C response to a specific statin dose.
- High-intensity statin therapy reduces ASCVD events more than moderate-intensity therapy, though lower-intensity statin therapy has also been shown to reduce ASCVD events (just to a lesser degree).
- To ensure the greatest benefit from therapy, patients should generally be treated with the maximum appropriate intensity of a statin that is tolerated, provided there are no contraindications or safety issues (i.e., drug-drug interactions).

# Statin Therapy Intensity

High-Intensity Statin Therapy	Moderate-Intensity Statin Therapy	Low-Intensity Statin Therapy
Daily dose lowers LDL-C, on average, by approximately $\geq 50\%$	Daily dose lowers LDL-C, on average, by approximately 30% to $< 50\%$	Daily dose lowers LDL-C, on average, by $< 30\%$
<b>Atorvastatin (40<sup>+</sup>)–80 mg</b> <b>Rosuvastatin 20 (40) mg</b>	Atorvastatin 10 (20) mg Rosuvastatin (5) 10 mg Simvastatin 20–40 mg <sup>‡</sup> Pravastatin 40 (80) mg Lovastatin 40 mg <i>Fluvastatin XL 80 mg</i> <b>Fluvastatin 40 mg BID</b> <i>Pitavastatin 2–4 mg</i>	<i>Simvastatin 10 mg</i> <b>Pravastatin 10–20 mg</b> <b>Lovastatin 20 mg</b> <i>Fluvastatin 20–40 mg</i> <i>Pitavastatin 1 mg</i>



# Statin Side Effects

My patients are often concerned about problems with treatment and reluctant to even consider therapy.

How do you address potential side effects from statin medications?

# Statin Side Effects

Key Points to Monitoring Statin Effects and Side Effects include:

- First review heart-healthy lifestyle habits
- Assess adherence
- Response to therapy
- Adverse effects within 4 to 12 weeks following statin initiation or change in therapy
- Measure fasting lipid levels
- Unless symptomatic, do not routinely monitor creatine kinase levels
- If ALT and/or AST are  $\geq 3x$  ULN, decrease or stop statin and consider other causes of liver disease; otherwise when statin dose is optimized and ALT and AST are  $\leq 3x$  ULN normal liver enzymes do not need to be repeated.
- Screen for and treat type 2 diabetes according to current guidelines

# Communicate Risk

- A discussion of the magnitude of risks versus the loss of benefit from the statin is an integral part of the provider-patient relationship.
- Involving patients in the decision-making process to arrive at a solution may help increase their compliance with the treatment plan.
  - **Liver complaints:** If ALT and/or AST are  $\geq 3x$  ULN, decrease or stop statin and consider other causes of liver disease; otherwise when statin dose is optimized and ALT and AST are  $\leq 3x$  ULN normal liver enzymes do not need to be repeated.
  - **Diabetes:** Statin treatment slightly increases the risk of developing diabetes. Benefits generally outweigh the risks.
  - **Muscle complaints:** Warn patients taking statins to report worsening muscle pain without delay. Reassure them that prompt attention to this symptom can minimize an otherwise serious side effect.

## Statin-Associated Muscle Symptoms (SAMS)

- Exclude conditions with similar symptoms (arthritis, tendinitis, chronic pain)
- A 2-week statin-free period can help identify statin-intolerant patients
- Avoid medication interactions which increase SAMS
  - CYP3A4 inhibitors, gemfibrozil, cyclosporins, fibrates and niacin
- Supplements given with statins are not well-supported by RCTs, but:
  - Vitamin D is inexpensive and low levels are associated with myalgias
  - CoQ10 is often reported to provide relief from MS symptoms
- Intermittent statin dosing can still reduce LDL-C by 20-40%
  - Statins with longer half-lives (rosuvastatin, pravastatin) could be initially dosed once weekly and up-titrated to as frequently as every other day dosing
- Ezetimibe is an alternative in the truly statin-intolerant patient
  - Advise patients Rx is not a statin, and has a low incidence of MS symptoms

# Challenging Patients

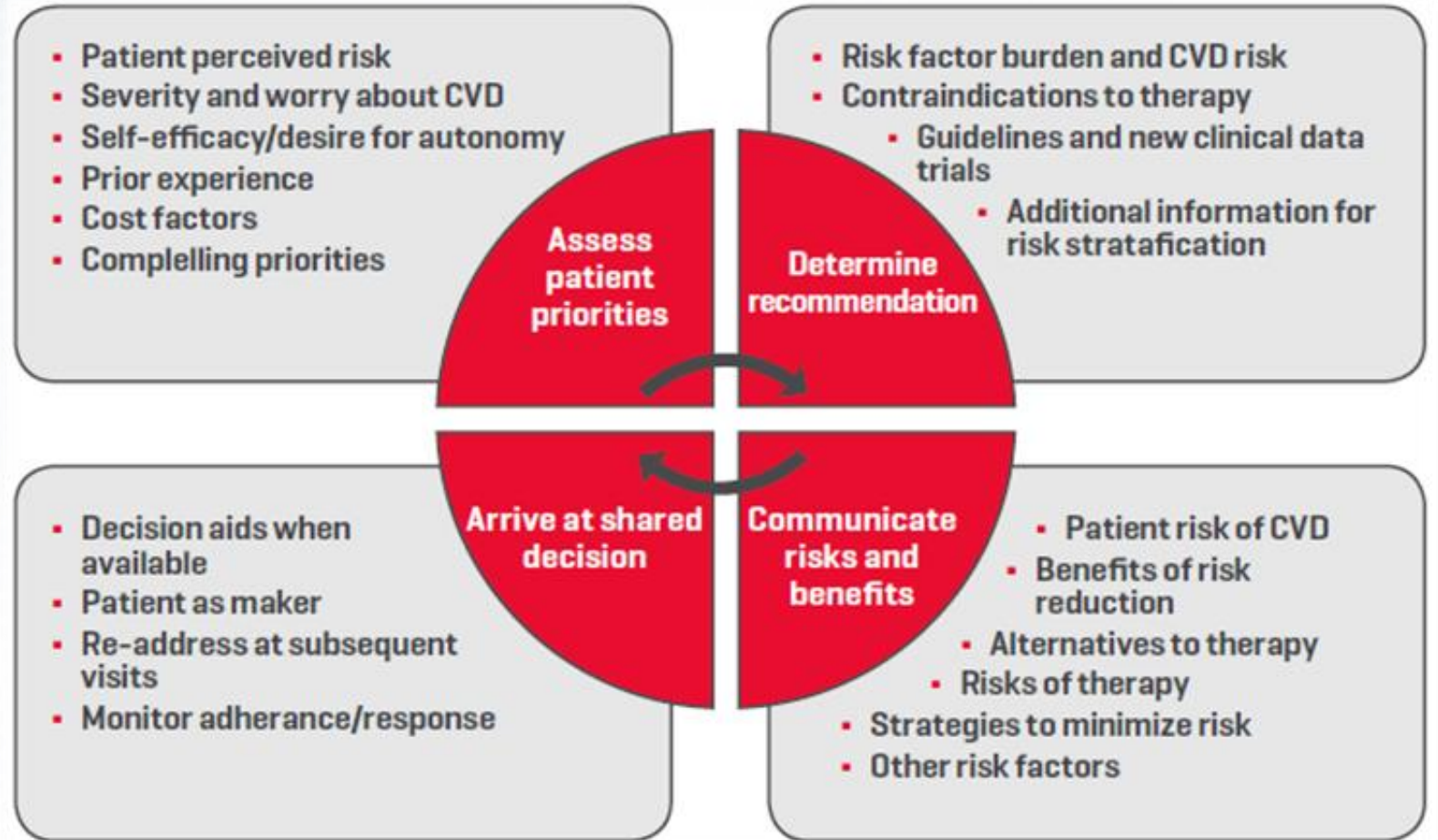
Some of my patients seem to be unwilling to even consider treatment.

How can I approach these patients?

# Patient Centered Care

## Strategies for success:

- Identify the patient's preferences and values
- Communicate simple information to the patient
- Involve the patient's family / friends in the discussion



# Lifestyle and Risk

- The following lifestyle changes are critical to ASCVD prevention and cholesterol management:
  - ✓ following a heart-healthy diet
  - ✓ exercising regularly
  - ✓ quitting and avoiding tobacco use
  - ✓ maintaining a healthy weight
- The benefits of lifestyle intervention can impact hypercholesterolemia, hypertension, diabetes and the risk of subsequent ASCVD events

# Optimizing Treatment

I sometimes have trouble getting LDL to goal.

What are the options for increasing the potency of treatment?



# LDL Goals

- Adults with known ASCVD
  - Lower LDL-C levels by  $\geq 50\%$  (LDL < 70 in high-risk ASCVD)
- Adults with DM, aged 40-79 years with an LDL-C level 70-189 mg/dL
  - Lower the LDL-C level by  $\geq 50\%$
- Adults with LDL-C level of > 190mg/dL
  - Lower the LDL-C level to <100
- Adults with LDL-C level of 70-189 mg/dL and a 7.5% or greater 10 year risk of developing ASCVD (without clinical ASCVD or DM)
  - If 10-year risk is 7.5-20%, reduce LDL-C levels by  $\geq 30\%$
  - If 10-year risk is  $\geq 20\%$ , reduce LDL-C levels by  $\geq 50\%$

# Optimizing Treatment

**Assess adherence and percentage response to LDL-C–lowering medications / lifestyle changes with repeat lipid measurement 4 to 12 weeks after statin initiation or dose adjustment, repeated every 3 to 12 months as needed.**

- Define responses to lifestyle and statin therapy by percentage reductions in LDL-C levels compared with baseline.
- In ASCVD patients at very high-risk, triggers for adding non-statin drug therapy are defined by threshold LDL-C levels  $\geq 70$  mg/dL ( $\geq 1.8$  mmol/L) on maximal statin therapy.

# Additional Therapy

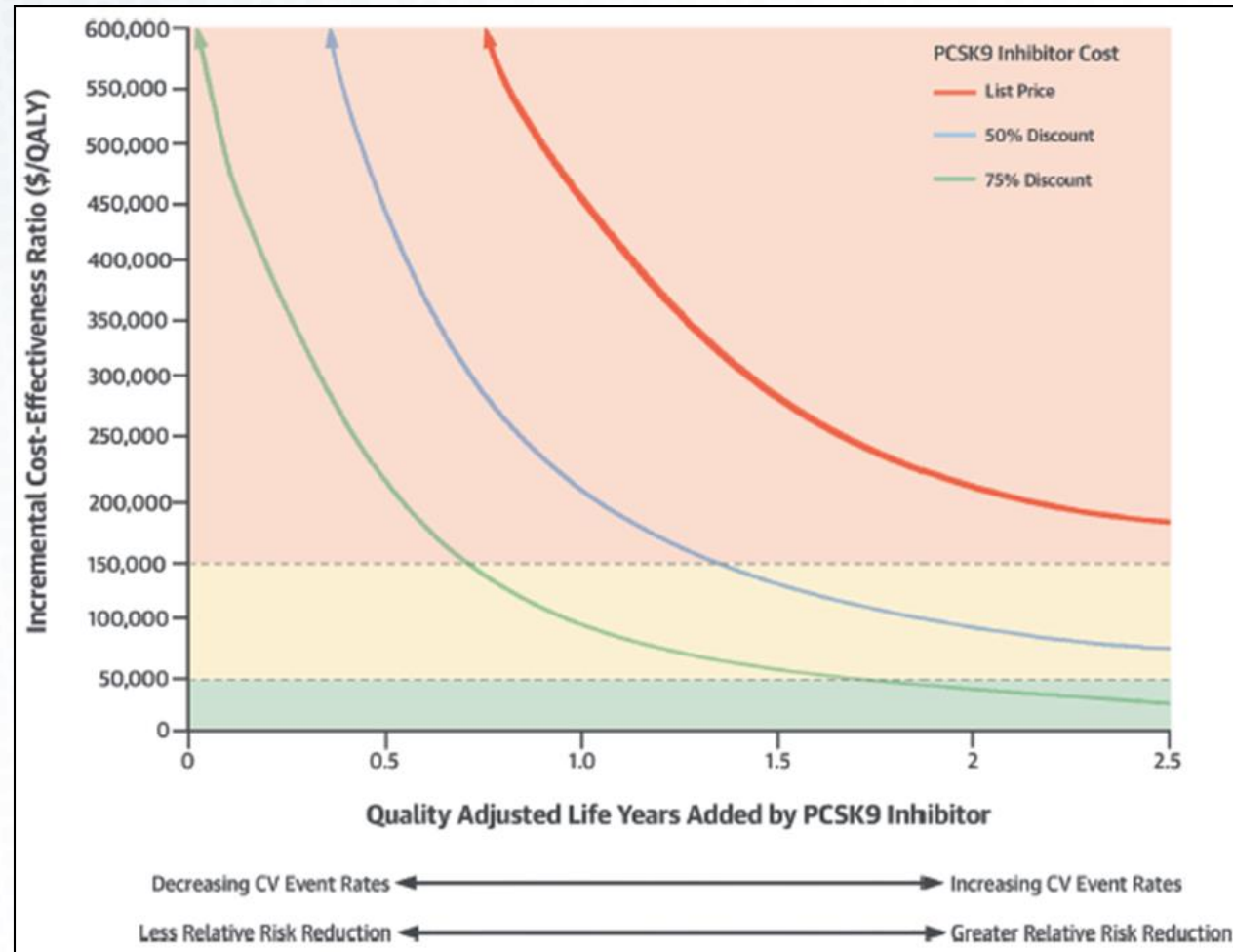
**In very high-risk ASCVD, use a LDL-C threshold of 70 mg/dL (1.8 mmol/L) to consider addition of non-statins to statin therapy.**

- Very high-risk includes a history of multiple major ASCVD events or 1 major ASCVD event and multiple high-risk conditions.
- In very high-risk ASCVD patients, it is reasonable to add ezetimibe to maximally tolerated statin therapy when the LDL-C level remains  $\geq 70$  mg/dL
- In patients at very high risk whose LDL-C level remains  $\geq 70$  mg/dL ( $\geq 1.8$  mmol/L) on maximally tolerated statin and ezetimibe therapy, adding a PCSK9 inhibitor is reasonable, although the long-term safety ( $>3$  years) is unclear and cost-effectiveness should be considered

# Trials of PCSK9 Inhibitors

Trial	Drug	Result
LONG TERM	Alirocumab in addition to maximally tolerated LLT	LDL reduced by 61% vs placebo
COMBO II	Alirocumab in addition to maximally tolerated LLT	LDL reduced by 50.6%
CHOICE I	Alirocumab in addition to maximally tolerated LLT	LDL reduced by 58.7%
LAPLACE-2	Evolocumab +/-statin	LDL reduced by 75%
GAUSS-2 Trial	Evolocumab, statin intolerant	LDL reduced by 56%
RUTHERFORD-2 Trial	Evolocumab in HeFH on maximally tolerated LLT	LDL reduced by 60%

# Cost-Effectiveness for PCSK9 Inhibitors



# Cholesterol Management: Summary

- Healthcare providers should assess atherosclerotic cardiovascular disease (ASCVD) risk in adults using evidence-based tools such as the ASCVD calculator to identify those at elevated risk who might benefit from treatment.
- Statins are the first line agents used to decrease cholesterol and reduce the risk of ASCVD events.
- Statin therapy is safe when used properly and monitored.
- Engage patients in the discussion before initiating statin therapy and when discussing lifestyle changes.
- Initiate the appropriate intensity of statin therapy to reduce ASCVD risk and regularly monitor patients for adherence to lifestyle and appropriate intensity of statin therapy.
- Non-statin drug therapy may be considered in combination or as monotherapy in selected individuals.

## Poll #2

How confident do you feel in initiating and addressing statin therapy gaps after this presentation?

- A. Very confident
- B. Confident
- C. Not confident
- D. Not very confident



# Questions?

Terence Offenberger, MD, MBA

Chris Champion, MD



# Thank You

- ▶ To receive CME/CEU credit for this session:  
Please submit the survey that will be sent to you after this webinar.
- ▶ For a copy of this presentation:  
Expect to receive a copy and a link to the recording via email in the next few days.
- ▶ Questions?  
Please email us at [NetworkQuality@scanhealthplan.com](mailto:NetworkQuality@scanhealthplan.com).