

August 19, 2019

COM-2019-036

Dear provider of pharmaceutical services,

The American Heart Association (AHA) and the American College of Cardiology (ACC) have released new guidelines on cholesterol management to reduce the risk for atherosclerotic cardiovascular disease (ASCVD).

Of important note, a major focus has been made in the beginning of a healthy lifestyle in childhood and its maintenance throughout life, which can reduce the risk for ASCVD at all ages. Additional key recommendations include:

FIRST RECOMMENDATION

Begin a healthy lifestyle in childhood and maintain it throughout life.

- For secondary prevention in patients with ASCVD, treatment with statins at maximally tolerated or high-intensity doses to reduce low-density lipoprotein cholesterol (LDL-C) level.
 - Statin therapy goal: Reduce LDL-C level by a mean of $\geq 50\%$.
- For very high-risk patients, defined as a history of multiple major ASCVD events or one major ASCVD event and other high-risk comorbidities, treatment with non-statin therapies plus statins.
 - Proposed threshold for the addition of non-statin therapies: LDL-C level of 1.8 mmol/L (70 mg/dL).
- For patients with primary, severe hypercholesterolemia, defined as an LDL-C level ≥ 4.9 mmol/L (≥ 190 mg/dL), treatment with maximally tolerated statin therapy to reduce LDL-C level toward a lower risk range.
 - Calculating 10-year ASCVD risk is not necessary.
- For patients aged 40 to 75 years with diabetes mellitus who have an LDL-C level ≥ 1.8 mmol/L (70 mg/dL), treatment with a moderate-intensity statin.
 - Calculating 10-year ASCVD risk is not necessary.
- For patients with diabetes mellitus and higher risk (e.g. multiple risk factors or aged 50 to 75 years), treatment with a high-intensity statin is reasonable to reduce the LDL-C level by at least 50%.

NON-STATIN THERAPIES

Intestinal cholesterol absorption inhibitor: Ezetemibe.

Proprotein convertase subtilistin/kexin type 9 (PCSK9) inhibitor: Alirocumab, Evolocumab.

- For patients aged 40 to 75 years without diabetes mellitus who have an LDL-C level of at least 1.8 mmol/L (70 mg/dL), and a 10-year ASCVD risk of $\geq 7.5\%$, treatment with a moderate-intensity statin if its use is favored after a discussion of treatment options.
- For primary prevention in patients aged 40 to 75 years, the guideline endorsed a 3-tiered decision process. Figure 1 shows a flow diagram for primary prevention of ASCVD.

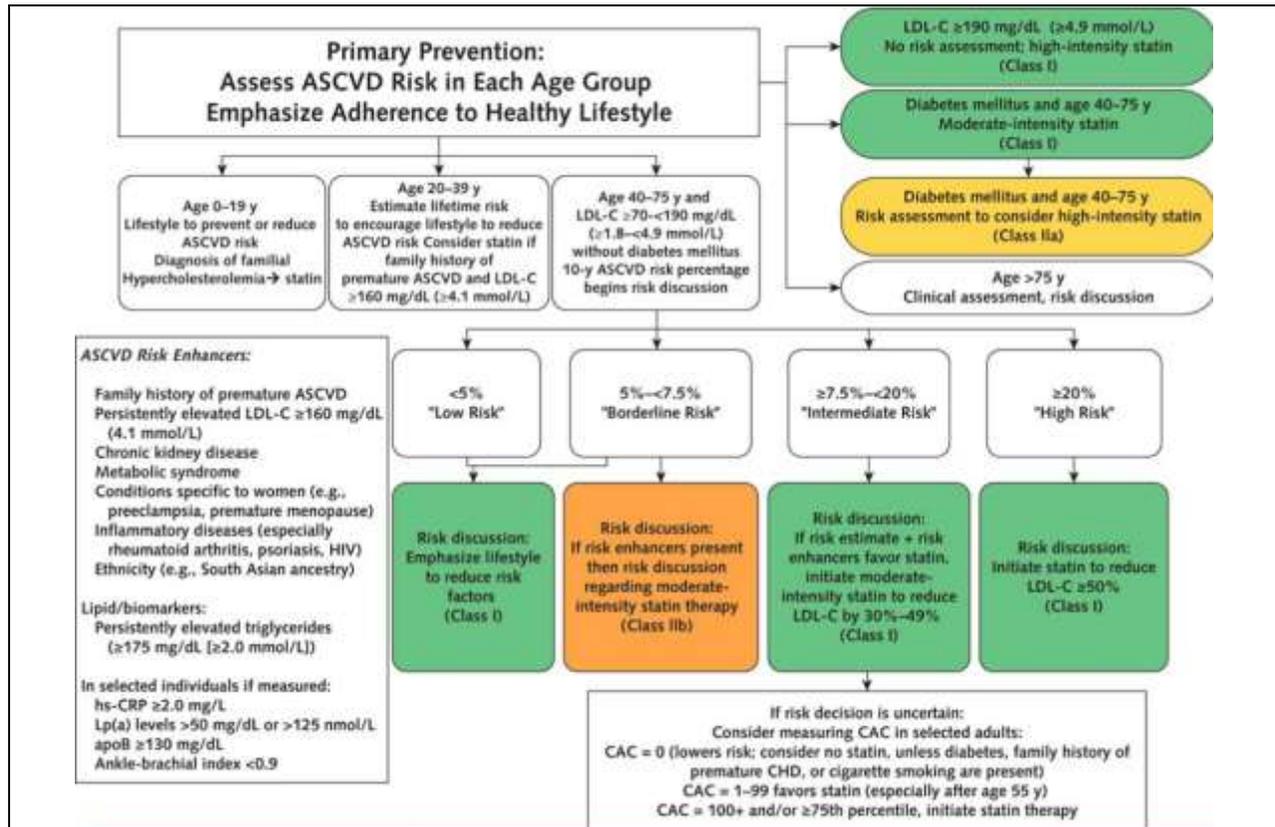


Figure 1. Flow diagram for primary prevention of ASCVD. (Image from: Grundy, S., & Stone, N. (2019). 2018 Cholesterol Clinical Practice Guidelines: Synopsis of the 2018 American Heart Association/American College of Cardiology/Multisociety Cholesterol Guideline*. Annals Of Internal Medicine, 170(11), 779. doi: 10.7326/m19-0365.)

In addition, the guideline included recommendations for ensuring statin safety by performing a clinician-patient risk discussion before initiating statin therapy (Table 1).

Table 1. Risk Discussion Topics
Review of major risk factors. †
Risk-enhancing factors. ‡
Potential benefits of lifestyle and statin therapies.
Potential for adverse effects and drug–drug interactions.
Consideration of costs of statin therapy.
Patient preferences and values.

† Major risk factors: Cigarette smoking and elevated levels of blood pressure, LDL-C, hemoglobin A1C level [if indicated], or calculated 10-year risk for ASCVD.

‡ Risk-enhancing factors: Family history of premature ASCVD, LDL-C levels of ≥ 4.1 mmol/L (160 mg/dL), metabolic syndrome, chronic kidney disease, history of preeclampsia or premature menopause (in women), chronic inflammatory disorders, high-risk ethnicity (e.g. South Asian ancestry), triglyceride levels persistently elevated above 2.0 mmol/L (175 mg/dL), elevations in apolipoprotein B, high-sensitivity C-reactive protein levels of ≥ 19.0476 nmol/L (2.0 mg/L), lipoprotein levels with elevations above 125 nmol/L (50 mg/dL), or reduced ankle–brachial index.

For more details regarding AHA/ACC recommendations, the guideline synopsis was published in the Annals of Internal Medicine and is available at <https://annals.org/aim/fullarticle/2734785/2018-cholesterol-clinical-practice-guidelines-synopsis-2018-american-heart-association>.

Remember, medical literature is dynamic and is continuously changing as new scientific knowledge is developed. We exhort the frequent revision of treatment guidelines to assure that our recommendations are consistent with the most actualized information.

In PharmPix we are compromised with the health and wellness of our insured. It is our priority to offer high quality services and to promote practices for health promotion and diseases prevention. If you have any doubt or wish to have more information regarding this document, you can call us to 787-522-5252, extension 137.

Regards,

Clinical Department

References:

1. AHA, ACC Release New Clinical Guidelines on Cholesterol Management. (2019). Managed Care. Retrieved from <https://www.managedhealthcareconnect.com/content/aha-acc-release-new-clinical-guidelines-cholesterol-management>
2. Grundy, S., & Stone, N. (2019). 2018 Cholesterol Clinical Practice Guidelines: Synopsis of the 2018 American Heart Association/American College of Cardiology/Multisociety Cholesterol Guideline*. Annals Of Internal Medicine, 170(11), 779. doi: 10.7326/m19-0365.
3. May, B. (2019). Synopsis of the Updated AHA/ACC Guideline for ASCVD Risk Reduction - Clinical Advisor. Retrieved from <https://www.clinicaladvisor.com/home/topics/cardiovascular-disease-information-center/aha-acc-publish-guideline-for-cholesterol-management-ascvd-risk-reduction/>