

**P&T Committee
Written Public Testimony
October 7, 2026**

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Check here if you are representing or speaking on behalf of any company/organization.

True

Check here if you are a private practice physician not affiliated with any manufacturer/organization.

False

Check here if you are a member of the public not affiliated with any manufacturer/organization.

False

Please check the box of the statement that best applies

I have a financial interest, affiliation or am employed by an organization that may have a direct interest in the business before the AHCCCS P&T Committee.

If yes, name organizations and roles:

Amgen Employee

Medical Value & Access Liaison

Summary of Testimony*

Dear Arizona AHCCCS Pharmacy & Therapeutics Committee,

In response to the upcoming P&T committee posted agenda, Amgen kindly requests consideration of the following information for Repatha® (evolocumab).

Repatha® is a proprotein convertase subtilisin/kexin type 9 inhibitor

(PCSK9i) indicated:(1)

- o To reduce the risk of major adverse CV events (CV death, MI, stroke, unstable angina requiring hospitalization, or coronary revascularization) in adults at increased risk for these events
 - o As an adjunct to diet and exercise to reduce LDL-C in:
 - o Adults with hypercholesterolemia
 - o Adults and pediatric patients aged 10 years and older with HeFH
 - o Adults and pediatric patients aged 10 years and older with HoFH
- The safety and effectiveness of Repatha® have not been established in pediatric patients with HeFH or HoFH who are younger than 10 years old or in pediatric patients with other types of hypercholesterolemia.¹

The updated indication now includes adults at increased risk for MACE, including cardiovascular death, myocardial infarction, stroke, unstable angina requiring hospitalization, or coronary revascularization, without the prior requirement for established cardiovascular disease.

Clinical Updates

Repatha is now the first and only PCSK9 inhibitor shown to reduce the risk of MACE in patients at high CV risk without prior MI or stroke. This new CV outcomes data comes from the VESALIUS-CV phase 3 trial of approximately 12,000 patients at high CV risk without prior MI or stroke. Enrolled patients had at least one of the following disease categories: coronary artery disease, high-risk diabetes mellitus, peripheral artery disease, or atherosclerotic cerebrovascular disease and at least one additional high-risk criteria. The topline result was that evolocumab plus optimized lipid-lowering therapy significantly reduced the risk of composite MACE events compared to optimized lipid-lowering therapy alone. There was a 25% Relative Risk Reduction in the 3-point MACE (time to first occurrence of coronary heart disease death, MI, or ischemic stroke) for patients receiving evolocumab. There was also a 19% relative risk reduction in the 4-point MACE (time to first occurrence of coronary heart disease death, MI, ischemic stroke, or ischemia-driven arterial revascularization). Evolocumab also reduced the risk of a first MI by 36%. Evolocumab lowered LDL-C by a mean of 55% vs placebo with the median LDL-C at 48 weeks of 45 mg/dL (evolocumab group) vs 109 mg/dL (placebo group). Reported serious adverse events were 28.2% for evolocumab vs 28.9% for placebo. Adverse events leading to study drug discontinuation occurred in 3.3% and 3.7% for evolocumab and placebo, respectively.⁽²⁾

Additionally, in a pre-specified exploratory subgroup analysis of high-risk patients without known significant atherosclerosis and with diabetes (who comprised ~30% of the overall study population), addition of evolocumab to baseline lipid lowering therapy resulted in a median LDL-C of 44 mg/dL compared to 105 mg/dL for placebo, a 31% RRR in both 3-P and 4-P MACE endpoints, and a 32% RRR in CV death, MI, or ischemic stroke. Reported serious AEs were comparable between groups.⁽³⁾

Highlights from Relevant Guidelines

The recently updated 2026 AHA/ACC Guideline on the Management of Dyslipidemia re-established LDL-C goals, and reinforced that earlier, more intensive LDL-C lowering is essential for reducing cardiovascular risk. The guideline

recommends LDL-C goals of < 70 mg/dL for adults aged 40-75 with diabetes and multiple ASCVD risk factors (or in adults with diabetes and 10-year ASCVD risk of $\geq 10\%$ by the PREVENT-ASCVD equations), as well as for ASCVD patients not at very high risk and <55 mg/dL for secondary prevention in patients at very high-risk (majority of patients with clinical ASCVD). Updates to treatment sequencing with non-statin therapies, enable earlier initiation of PCSK9i mAbs in select patient populations, including equal placement with ezetimibe (and in some cases, bempedoic acid). Ezetimibe is no longer placed prior to a PCSK9i mAb like Repatha for many patient groups. Additionally, coronary artery calcium (CAC) scoring is utilized to improve risk assessment and guide treatment decisions in patients with subclinical atherosclerosis.(4) Separately, the 2026 ADA clinical guidelines recommend a PCSK9i, like Repatha®, or ezetimibe in patients with diabetes ages 40 to 75 who are at high CV risk and on a high-intensity statin but have not achieved LDL-C < 70 mg/dL with a 50% reduction from baseline.(5)

Repatha Prior Authorization

Repatha® has an established safety profile and reduces the risk of CV events in adults with established CV disease and has been studied in 51 clinical trials involving > 57,000 patients in both the Repatha® and comparator groups. Given the reduction in MACE seen in VESALIUS-CV, guideline recommendations, and the fact that LDL-C is a modifiable risk factor warranting greater attention in patients at high CV risk, we respectfully ask that the Repatha® prior authorization criteria be revised to remove the ezetimibe step requirement for ASCVD patients. Ezetimibe used in combination with a statin therapy results in approximately 25% LDL-C lowering and approximately 15%-20% reduction when used as monotherapy and may benefit patients who require less intensive LDL-C lowering (LDL-C, 70 – 99 mg/dL). Additionally, please consider removing the specialist consultation requirement that may lead to delays and under-treatment especially for those living in rural areas.

Thank you for your review of this information in support of appropriate access to Repatha aligned with the prescribing information.

References

1. Repatha® (evolocumab) Prescribing Information.
2. Bohula EA, et al. New Engl J Med. 2026;394:117-127.
3. Marston NA et al. JAMA. 2026;335:1400-1407.
4. Blumenthal RS, et al. 2026 ACC/AHA/Multisociety Guideline on the management of Dyslipidemia. J Am Coll Cardiol. 2026;87:2625-2757.
5. American Diabetes Association Professional Practice Committee. Diabetes Care. 2025;48(Suppl 1):S207-S238.

Drug/product*

Repatha (evolocumab)

Therapeutic Drug Class*

Lipotropics, Other

Testimony Format*

Written

Are you an employee or principal member of a company that is testing, producing, marketing, re-selling or distributing health care goods or services?

Yes

Do you receive currently, or have you received in the past 12 months, payments from a company for any of the following or similar work you provided: speakers' bureau, consultant, grant/research, etc.

No

In your presentation, will you discuss any products or services that were developed by a commercial interest (e.g. pharmaceutical company or device manufacturer) with which, within the past 12 months, you, your spouse, or your partner have had a financial relationship?

Yes

Will you be discussing off-label use(s) of a medication? If so, identify the medication, off-label use, YES NO and manufacturer.

No

Do you have any other kind of financial interest in products or services you will be discussing?

No

If you answered "Yes" to any of the above, please list the commercial interest(s) and define your relationship(s) (e.g., founder, chief medical officer, speakers' bureau, consultant, research support, stocker holder, royalties, or similar).

Amgen Employee

Medical Value & Access Liaison