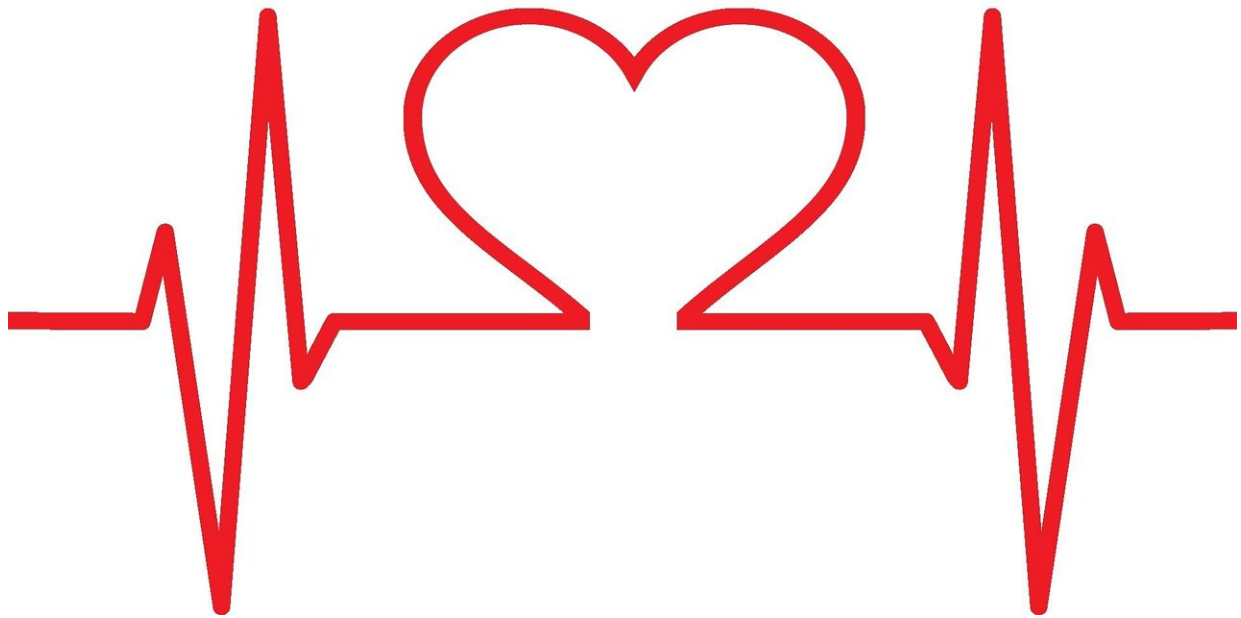


Ezetimibe reduces the risk of heart attacks and strokes

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Patients with a history of coronary heart disease (CHD) or acute coronary syndrome (ACS) benefit more from treatment with a statin in combination with ezetimibe than from treatment with a statin alone. However, there is no hint that the combination therapy of a statin plus ezetimibe is also superior to the combination of a statin plus the lipid-lowering drug alirocumab. No studies on other lipid-lowering combination options were available.

These are the findings of the German Institute for Quality and Efficiency in Health Care (IQWiG) in a current benefit assessment commissioned by the Federal Joint Committee (G-BA) in November 2018.

The most common cause of death worldwide

Cardiovascular diseases are diseases that originate from the vascular system and/or the heart. These include hypertension, CHD, ACS, heart attack and stroke. Cardiovascular diseases were the most common cause of death worldwide in 2016, accounting for 31 percent of all deaths. Of these causes of death, 85 percent resulted from a heart attack or stroke.

One of the largest modifiable risk factors for cardiovascular diseases is a high LDL cholesterol level (LDL = low-density lipoprotein). The reduction in LDL cholesterol (LDL-C) is therefore an important goal in the prevention of cardiovascular diseases. In patients with a history of CHD or ACS, the administration of cholesterol-lowering drugs is recommended. Statins are currently the most commonly prescribed group of drugs in this regard.

For some time now, a combination of statin and [ezetimibe](#) has also been used to further reduce LDL cholesterol. The German Federal Institute for Drugs and Medical Devices (BfArM) approved this extension of the therapeutic indication for ezetimibe in patients with a history of CHD and ACS in 2016.

One relevant large study for each question

On behalf of the G-BA, the IQWiG researchers investigated the benefit of treatment with ezetimibe in combination with a statin to reduce the risk of cardiovascular events in patients with a history of CHD or ACS

with regard to patient-relevant outcomes—versus treatment with a statin alone (research question 1) and—versus treatment with a combination of a statin and another drug influencing lipid metabolism (research question 2).

The assessment of research question 1 was ultimately based only on the IMPROVE-IT study. The other studies identified did not contain any relevant additional information. The IMPROVE-IT study included 18,144 patients who had experienced an ACS within 10 days prior to randomization. The study was designed to examine the effect of ezetimibe on [clinical outcomes](#) (the primary outcome was a combined outcome of fatal and non-fatal cardiovascular events) rather than on surrogate outcomes (such as a reduction in LDL-C). The median follow-up period was six years.

For research question 2, the IQWiG researchers identified COMBO II as the only relevant study. This randomized controlled trial included 720 patients with a high to very high cardiovascular risk whose LDL-C levels were insufficiently controlled with an existing statin therapy. The primary outcome of the study was the change in LDL-C levels after 24 weeks compared with baseline. The "other drug influencing lipid metabolism" was [alirocumab](#).

Fewer heart attacks and fewer strokes than with statin monotherapy

In patients with a history of CHD or ACS, the IQWiG researchers see an indication of a greater benefit of ezetimibe in combination with a statin versus a statin alone (research question 1). For these patients, the additional administration of ezetimibe reduces the risk of suffering a major adverse cardiovascular event. In the benefit assessment, serious adverse cardiovascular events were evaluated as a combined outcome of

the patient-relevant components of cardiovascular death, non-fatal myocardial infarction, and non-fatal stroke.

For other patient-relevant outcomes such as all-cause mortality, hospitalization for unstable angina pectoris, hospitalization for heart failure or other serious adverse events, however, the IMPROVE-IT study showed no statistically significant difference between treatment groups.

No superiority over alirocumab plus statin

In patients with a history of CHD or ACS, the IQWiG project team found no hint that the combination therapy of a statin plus ezetimibe was also superior to the [combination](#) of a [statin](#) plus alirocumab (research question 2).

For the combined outcome "major adverse cardiovascular event," the COMBO II study did not provide data for the relevant subpopulation. Therefore, the IQWiG team assessed the individual components separately: for "non-fatal myocardial infarction," "fatal and non-fatal stroke" and "hospitalization due to unstable angina pectoris," there were no statistically relevant differences between the treatment groups. However, due to the relatively small number of patients, the data are just as inadequate as for the outcome "all-cause mortality."

Provided by Institute for Quality and Efficiency in Health Care

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