

IQWiG Reports - Commission No. H20-07

Coronary lithoplasty for coronary heart disease¹

Extract

¹ Translation of the executive summary of the §137h assessment: H20-07 *Koronare Lithoplastie bei koronarer Herzkrankheit* (Version 1.0; Status: 25 February 2021). Please note: This translation is provided as a service by IQWiG to English-language readers. However, solely the German original text is absolutely authoritative and legally binding.

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IQWiG thanks the medical expert advisor for his contribution to the §137h assessment. However, the advisor was not involved in the preparation of the §137h assessment. IQWiG is solely responsible for the content of the §137h assessment.

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Executive summary

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the method "coronary lithoplasty for coronary heart disease" according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The assessment documents were submitted to IQWiG on 14 January 2021.

According to the information in the submission form, coronary intravascular lithoplasty aims to prepare calcified lesions in coronary arteries for dilatation of a coronary artery stenosis with low balloon pressure and subsequent implantation of a stent.

Ten studies with results were available for the assessment, including 8 case series, 1 systematic review containing case series and 1 single-case report, as well as 1 analysis of pooled data from 2 of the case series. In addition, reference was made to 11 studies for which results were not yet available.

Findings on the benefit, ineffectiveness or harmfulness of coronary intravascular lithoplasty could not be derived from the data submitted, as no comparative data were available. Likewise, the supplemental examination of the results of the case series did not suggest that the method is harmful.

Overall, in this assessment according to §137h, based on the documents submitted neither a benefit, harmfulness nor ineffectiveness of coronary intravascular lithoplasty for patients with calcified, non-pretreated coronary stenoses can be identified.

A testing study suitable to provide the necessary findings to assess the benefit of the method is possible in principle. A large randomized controlled trial in patients with calcified, non-pretreated coronary stenoses and a medical indication for percutaneous coronary intervention is required. The study objective would be to compare coronary intravascular lithoplasty with alternative preparation techniques in terms of prevention of major cardiovascular events.

The full report (German version) is published under

https://www.iqwig.de/en/projects/h20-07.html