IQWiG Reports – Commission No. H20-06

Percutaneously implanted interatrial shunt for the treatment of heart failure[1]

Extract

[1] Translation of the executive summary of the §137h assessment: H20-06 *Perkutan-implantierter interatrialer Shunt zur Behandlung der Herzinsuffizienz* (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. 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 "percutaneously implanted interatrial shunt for the treatment of heart failure (HF)" according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The assessment of the method was to be limited to the patient population of HF with reduced left ventricular ejection fraction (LVEF < 40%) (HFrEF). The assessment documents were submitted to IQWiG on 14 January 2021.

According to the submission form, the interatrial shunt is intended for the treatment of patients with symptomatic HF (New York Heart Association [NYHA] classes III-IV) with HFrEF and preserved (LVEF > 40%) left ventricular ejection fraction (LVEF) (HFpEF). It is a permanent implant for patients with HF and, according to the information in the submission form, aims to regulate the blood flow from the left to the right atrium, thereby improving symptoms in these patients.

A total of 10 studies with results and 1 comparison of 2 studies were available, of which 3 case series could be used to a limited extent for the assessment in HFrEF patients.

Findings on the benefit, ineffectiveness or harmfulness of a percutaneously implanted interatrial shunt could not be derived from the data submitted, as no evaluable comparative data were available. Likewise, the supplemental examination of the results of the case series did not suggest that such a shunt in patients with HF is harmful. Overall, in this assessment according to §137h, based on the documents submitted neither a benefit, harmfulness nor ineffectiveness of a percutaneously implanted interatrial shunt in patients with HF can be identified.

A testing study suitable to provide the necessary evidence to assess the benefit of the method is possible in principle. However, the submission form refers to 3 ongoing randomized controlled trials (RCTs) on the method. Of these, the ongoing RELIEVE-HF study seems to be suitable to provide the necessary results in the near future (and with participation of several German study centres) to assess the benefit and harm of an implanted interatrial shunt in patients with HF with a limited ejection fraction. Under the premise that the RELIEVE-HF study is conducted and completed as planned and that analyses of patient-relevant outcomes are presented for the requested target population, a separate testing study is currently not considered necessary.

The full report (German version) is published under

https://www.iqwig.de/en/projects/h20-06.html