# Percutaneously implanted interatrial shunt for the treatment of heart failure with reduced left ventricular ejection fraction (LVEF < 40%)

Addendum to project N24-04
(rapid report)[1]

**EXTRACT**

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[1] Translation of the key statement of the addendum N25-07 *Perkutan implantierter interatrialer Shunt zur Behandlung der Herzinsuffizienz mit reduzierter linksventrikulärer Ejektionsfraktion (LVEF < 40 %) – Addendum zum Projekt N24-04 (Rapid Report);* (Version 1.0; Status: 8 January 2026). 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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**Key statement**

On 9 October 2025, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out a supplementary assessment of project N24-04 (percutaneously implanted interatrial shunt for the treatment of heart failure with reduced left ventricular ejection fraction [LVEF < 40%]) [1] (and the associated assessments H20-06 [2] and H21-05 [3]) in order to assess the subsequently submitted results of the RELIEVE-HF trial.

**Research question**

The aim of this investigation is

- to assess the benefit of treatment with a percutaneously implanted interatrial shunt in addition to guideline-based drug therapy, compared with guideline-based drug therapy alone

in patients with heart failure and reduced LVEF (< 40%) (HFrEF) and elevated left atrial pressure, who remain symptomatic despite guideline-based drug therapy.

**Conclusion**

This assessment included one randomized controlled trial (RELIEVE-HF) comparing interatrial shunts with standard drug therapy alone, with data from a total of 206 patients with heart failure and reduced LVEF (≤ 40%).

On the basis of the comprehensive study data from the RELIEVE-HF trial, there was an indication of a greater benefit in terms of hospitalizations (heart failure-related and total hospitalizations). The conclusion about benefit relates to patients with New York Heart Association (NYHA) Class III heart failure, as they account for 95% of the study population.

However, with regard to the outcome categories of mortality and health-related quality of life – which are considered essential in this therapeutic indication – no advantages were observed (no hint of benefit or harm). There was no hint of greater benefit or harm associated with the interatrial shunt for other outcomes investigated – in particular, health status, physical capacity and serious adverse events.

Taking all the results together, there is therefore an overall hint that treatment using a percutaneously implanted interatrial shunt, in addition to guideline-based drug therapy, offers greater benefit than guideline-based drug therapy alone.

**References for English extract**

Please see full addendum for full reference list.

1. Gemeinsamer Bundesausschuss. Perkutan implantierter interatrialer Shunt zur Behandlung der Herzinsuffizienz mit reduzierter linksventrikulärer Ejektionsfraktion (LVEF < 40 %) (§ 137e SGB V); Beauftragung IQWiG: Update/Rapid Report [online]. 2025 [Accessed: 11.03.2025]. URL: https://www.g-ba.de/bewertungsverfahren/methodenbewertung/245/#beauftragung-iqwig-update-rapid-report.

2. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Perkutan-implantierter interatrialer Shunt zur Behandlung der Herzinsuffizienz; Bewertung gemäß § 137h SGB V [online]. 2021 [Accessed: 06.05.2025]. URL: https://www.iqwig.de/download/h20-06_perkutan-implantierter-interatrialer-shunt-zur-behandlung-der-herzinsuffizienz_bewertung-137h-sgb-v_v1-0.pdf.

3. Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Perkutan implantierter interatrialer Shunt zur Behandlung der Herzinsuffizienz; Addendum zum Auftrag H20-06 [online]. 2021 [Accessed: 06.05.2025]. URL: https://www.iqwig.de/download/h21-05_perkutan-implantierter-interatrialer-shunt-zur-behandlung-der-herzinsuffizienz_addendum-zum-auftrag-h20-06_v1-0.pdf.

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