

# In-toto thrombectomy using retriever / aspiration system for acute pulmonary artery embolism<sup>1</sup>

Addendum to Project H22-04

# **EXTRACT**

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<sup>&</sup>lt;sup>1</sup> Translation of the executive summary of the addendum H23-01 *In-toto-Thrombektomie mittels Retriever-/ Aspirationssystem bei akuter Lungenarterienembolie - Addendum zum Projekt H22-04* (Version 1.0; Status: 20 March 2023). 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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# **Keywords**

Thrombectomy, Pulmonary Embolism, Device Approval, Risk Assessment, Benefit Assessment

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#### **Executive summary**

In a letter dated 20 January 2023, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG), as an addendum to commission H22-04, to review the conclusions of the assessment according to §137h Social Code Book (SGB) V on the benefit, harmfulness and ineffectiveness of the method "in-toto thrombectomy using a retriever / aspiration system for acute pulmonary artery embolism".

#### Research question

The aim of the present investigation was to determine whether further relevant studies on the method "in-toto thrombectomy using a retriever / aspiration system for acute pulmonary artery embolism" exist besides the documents already used in the §137h assessment H22-04. If this was the case, it was to be examined whether, taking these into account, still neither a benefit, harmfulness nor ineffectiveness could be identified for the examination or treatment method in question. Furthermore, it was to be examined whether, besides the studies already used in the §137h assessment, ongoing studies exist that are in principle suitable to provide relevant findings on the benefit, harmfulness or ineffectiveness of the method in the near future.

#### Methods

Randomized controlled trials (RCTs) were included that investigated the above method with regard to patient-relevant outcomes and that had not already been used in the assessment according to §137h.

A systematic literature search for studies was conducted in MEDLINE and the Cochrane Central Register of Controlled Trials. In parallel, a search for relevant systematic reviews was conducted in MEDLINE, the Cochrane Database of Systematic Reviews, the International HTA Database as well as on the websites of the National Institute for Health and Care Excellence (NICE) and the Agency for Healthcare Research and Quality (AHRQ). Pending the commission, the last search was conducted on 19 January 2023. In addition, the following information sources and search techniques were considered: study registries and screening of reference lists. The selection of relevant studies was performed by 2 reviewers independently of one another.

Information assessment and information synthesis and analysis were guided by the principles described in the Institute's General Methods.

#### Results

No additional relevant completed or ongoing studies were identified during information retrieval.

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The study registry entry for PEERLESS, an ongoing RCT already presented in the §137h assessment H22-04, shows that it has recently been updated. The updates have no influence on the evaluation made in the §137h assessment that meaningful results can be expected from this study in the foreseeable future to assess the benefit of the method in comparison to catheter-guided thrombolysis.

#### **Conclusion**

After systematic examination, there is still no evidence of a benefit, ineffectiveness or harmfulness of the method "in-toto thrombectomy using a retriever / aspiration system for acute pulmonary artery embolism". Beyond the studies already considered in the §137h assessment, no additional completed or ongoing studies were found that would in principle be suitable to provide evidence of a benefit, ineffectiveness or harmfulness in the near future.

The full report (German version) is published under

https://www.iqwig.de/en/projects/h23-01.html