

IQWiG Reports – Commission No. H18-01

**Ultrasound-guided high-  
intensity focused ultrasound  
for unresectable malignant  
neoplasms of the pancreas  
Second Addendum to Commission  
H16-02C<sup>1</sup>**

**Executive Summary**

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<sup>1</sup> Translation of the executive summary of the addendum *Sonografiegesteuerte hochfokussierte Ultraschalltherapie bei inoperablen bösartigen Neubildungen des Pankreas – 2. Addendum zum Auftrag H16-02C* (Version 1.0; Status: 24 April 2018). 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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## **Executive summary**

With its letter of 1 March 2018, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) with a supplementary assessment of commissions H16-02C and H17-03 in order to evaluate the conclusions on the potential (in terms of §137h Social Code Book [SGB] V) of the method of ultrasound-guided high-intensity focused ultrasound (USgHIFU) for unresectable malignant neoplasms of the pancreas.

### ***Research question***

The aim of the present research was to investigate whether there are further relevant studies for USgHIFU in unresectable malignant neoplasms of the pancreas besides the documents already used in the §137h assessment H16-02C and the addendum H17-03. If this was the case, it was to be evaluated whether, under their consideration, the present examination or treatment method still offers potential or if its benefit has already been sufficiently proven. Furthermore, it was to be evaluated whether, besides the studies already considered in the §137h assessment H16-02C and the addendum H17-03, there are any ongoing studies that in principle are suited to provide relevant findings on the benefit of the method in the near future.

Two of the original 3 research questions (see Chapter 1 of the full addendum) were relevant for this addendum:

- 1) USgHIFU as additional tumour-modifying or palliative therapy for patients with unresectable pancreatic cancer in comparison with chemotherapy or radiochemotherapy alone
- 2) USgHIFU as additional tumour-modifying or palliative therapy for patients with unresectable pancreatic cancer in comparison with palliative care alone if chemotherapy or radiochemotherapy are no longer an option or are rejected by the patient.

### ***Methods***

This assessment included randomized controlled trials (RCTs) that investigated USgHIFU in unresectable malignant neoplasms of the pancreas with regard to patient-relevant outcomes and that had not already been used in the framework of the assessment according to §137h (H16-02C) or the first addendum (H17-03).

For this purpose, a systematic literature search was performed in the databases MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials. At the same time, a search for relevant systematic reviews was conducted in the databases MEDLINE, Embase, the Cochrane Database of Systematic Reviews, the Database of Abstracts of Reviews of Effects, and the Health Technology Assessment Database. The search was conducted on 5 March 2018. In addition, systematic reviews and publicly accessible trial registries were searched.

The assessment, synthesis and analysis of information followed the principles described in the Institute's methods paper.

### ***Results***

The systematic literature search identified 2 additional relevant and completed studies for the first research question, and 1 additional relevant and completed study for the second research question. These studies were unsuitable to demonstrate a benefit, however. For the first research question, one relevant ongoing study was already available from the §137h assessment H16-02C. No additional relevant ongoing study was identified for either of the 2 research questions.

The results of the studies additionally identified did not change the evaluation with regard to the potential.

### ***Conclusion***

After a systematic evaluation and under consideration of the further completed studies identified, USgHIFU in unresectable malignant neoplasms of the pancreas still possesses potential, both as additional tumour-modifying or palliative therapy in comparison with chemotherapy or radiochemotherapy alone (research question 1) and as additional tumour-modifying or palliative therapy in comparison with palliative care alone (research question 2). Beyond those studies already considered in the §137h assessment and in the first assessment, no further completed studies were found that in principle would be suited to demonstrate a benefit of the method. For the first research question, one ongoing study was already available for the §137h assessment H16-02C. No conclusion is currently possible as to whether and in which time period this study will provide relevant findings on the first research question. For the second research question, no additional ongoing studies were identified that in principle would be suited to demonstrate a benefit of the method in the near future.

**Keywords:** high-intensity focused ultrasound ablation, pancreatic neoplasms, assessment of potential, benefit assessment

*The full report (German version) is published under <https://www.iqwig.de/en/projects-results/projects/non-drug-interventions/h-projekte/h18-01-ultrasound-guided-high-intensity-focused-ultrasound-for-malignant-neoplasms-of-the-pancreas-second-addendum-to-commission-h16-02c.8805.html>.*