

IQWiG Reports – Commission No. H17-03

**Ultrasound-guided high-
intensity focused ultrasound
therapy for malignant
neoplasms of the pancreas
Addendum to Commission H16-02C¹**

Executive Summary

¹ Translation of addendum H17-03 *Sonografiegesteuerte hochfokussierte Ultraschalltherapie bei bösartigen Neubildungen des Pankreas – Addendum zum Auftrag H16-02C*. 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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² Due to legal data protection regulations, employees have the right not to be named.

Executive summary

On 2 August 2017, the Federal Joint Committee (G-BA) wrote to the Institute for Quality and Efficiency in Health Care (IQWiG) to commission a supplementary assessment to Commission H16-02C.

The aim of the present research was to reinvestigate whether the method of ultrasound-guided high-intensity focused ultrasound therapy (USgHIFU) for malignant neoplasms of the pancreas shows a benefit or potential according to §137h Social Code Book V. This investigation was based on documents transmitted by the G-BA on this method.

The present addendum was primarily based on information provided in the documents submitted by the G-BA to IQWiG when commissioning the addendum. The G-BA had received these documents in the framework of a commenting procedure on a planned change in directives from relevant scientific societies or medical device manufacturers entitled to submit comments. IQWiG assessed these documents using the methods applied in the original §137h assessment and followed the principles described in the Institute's methods paper. The responsibility for the present assessment and its result lies solely with IQWiG.

Results from 8 documents additionally submitted on 8 additional studies were used for the assessment of USgHIFU in unresectable malignant neoplasms of the pancreas (1 with results on research question 1, 7 with results on research question 2 [including 1 on endocrine pancreatic tumours]).

For the **therapeutic indication of unresectable *exocrine* pancreatic carcinoma for which another tumour-modifying treatment is also an option** (research question 1), the results from 1 prospective cohort study indicated advantages of USgHIFU as additional treatment to chemotherapy with gemcitabine in comparison with gemcitabine treatment alone regarding the outcomes “overall survival” and “pain”. At the same time, no disadvantages were revealed regarding the outcomes “physical functioning” and “treatment-related adverse events”. Consequently, a potential of a required treatment alternative can be derived for USgHIFU in this therapeutic indication, which is mainly based on the available findings on the outcomes “overall survival” and “pain”.

For the **therapeutic indication of unresectable *exocrine* pancreatic carcinoma for which no other tumour-modifying treatment is an option or for which such treatment is rejected** (research question 2), results from 6 single-arm observational studies were available. These were unsuitable for the derivation of a potential because there were no directly comparative data or corresponding data on the adequate comparator intervention (palliative care) to classify the results, e.g. on overall survival and morbidity. However, the advantages shown within the first research question regarding alleviation of pain can be considered transferable to the treatment situation of palliative care alone, resulting in the derivation of a potential also in this case.

For **unresectable endocrine pancreatic carcinoma**, a single-arm observational study provided insufficient data to allow the derivation of a potential. It cannot be assumed from a medical point of view that the findings on exocrine tumours are applicable to endocrine tumours. This thus results in no potential.

No additional studies were transferred for the **neoadjuvant use of USgHIFU in borderline resectable pancreatic carcinoma** (research question 3). It cannot be assumed that the findings on unresectable exocrine pancreatic carcinoma are applicable to borderline resectable pancreatic carcinoma. This thus results in no potential.

A testing study suitable to obtain the necessary information for a benefit assessment of the method is basically possible.

The full report (German version) is published under <https://www.iqwig.de/en/projects-results/projects/non-drug-interventions/h-projekte/h17-03-ultrasound-guided-high-intensity-focused-ultrasound-for-malignant-neoplasms-of-the-pancreas-addendum-to-commission-h16-02c.7925.html>.