

IQWiG Reports – Commission No. H17-04

**Ultrasound-guided high-
intensity focused ultrasound
therapy for unresectable
secondary malignant
neoplasms of the liver and
intrahepatic bile ducts
Addendum to Commission H16-02E¹**

Executive Summary

¹ Translation of the executive summary of addendum H17-04 *Sonografiegesteuerte hochfokussierte Ultraschalltherapie bei sekundären bösartigen Neubildungen der Leber und der intrahepatischen Gallengänge – Addendum zum Auftrag H16-02E* (Version 1.0, Status: 29 September 2017). 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 H16-02E.

The aim of the present research was to reinvestigate whether the method of ultrasound-guided high-intensity focused ultrasound therapy (USgHIFU) for unresectable secondary malignant neoplasms of the liver and intrahepatic bile ducts 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 transmitted by the G-BA to IQWiG when commissioning the addendum. The G-BA had received these documents within 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 5 documents additionally transmitted on 5 studies as well as from 1 study from the original §137h assessment were considered in the assessment of USgHIFU in unresectable secondary malignant neoplasms of the liver and intrahepatic bile ducts.

These 6 studies were single-arm observational studies: 3 on the USgHIFU treatment method, and 3 on different ablative treatment methods regarded to be relevant comparator treatments (1 on radiofrequency ablation [RFA], 1 on laser-induced thermotherapy [LITT], and one on microwave ablation [MWA]). All studies investigated patients with liver metastases.

Since there were no studies of direct comparisons, it was examined whether the studies allowed an indirect comparison to be able to derive conclusions on the potential of USgHIFU treatment in the present therapeutic indication. This examination showed that such an indirect comparison was not possible in a meaningful way. The studies – insofar as corresponding information was available – turned out to be too different, particularly regarding the patients included, pretreatments, available treatment options and treatment strategies regarding concomitant treatment and subsequent treatment. In other cases, relevant information was missing on precisely these aspects. Hence, it would not be possible in an indirect comparison to assess which influencing factors caused potential differences between the results of the studies.

Hence, also under consideration of the studies additionally transmitted, the possible importance of USgHIFU for unresectable secondary malignant neoplasms of the liver and intrahepatic bile ducts cannot be assessed and no potential can be inferred.

In summary, the result of the §137h assessment H16-02E was not changed by the studies additionally transmitted. On the basis of the assessment documents provided, neither a benefit nor a potential of a required treatment alternative can be inferred for the treatment method of USgHIFU in secondary malignant neoplasms of the liver and the intrahepatic bile ducts.

The full report (German version) is published under

<https://www.iqwig.de/en/projects-results/projects/non-drug-interventions/h-projekte/h17-04-ultrasound-guided-high-intensity-focused-ultrasound-for-secondary-malignant-neoplasms-of-the-liver-and-the-intrahepatic-bile-ducts-addendum-to-commission-h16-02e.7926.html>