

IQWiG Reports – Commission No. H16-02D

# **Ultrasound-guided high-intensity focused ultrasound therapy for malignant neoplasms of the liver and intrahepatic bile ducts<sup>1</sup>**

## **Executive Summary**

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<sup>1</sup> Translation of the executive summary of the assessment according to §137h Social Code Book (SGB) V *Sonografiegesteuerte hochfokussierte Ultraschalltherapie bei bösartigen Neubildungen der Leber und der intrahepatischen Gallengänge* (Version 1.0; Status: 30 January 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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IQWiG thanks the medical-scientific advisor for his contribution to the §137h assessment. The sole responsibility for the content of this assessment lies with IQWiG.

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<sup>2</sup> Due to legal data protection regulations, employees have the right not to be named.

## Executive summary

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the method of ultrasound-guided high-intensity focused ultrasound therapy (USgHIFU) for primary malignant neoplasms of the liver and intrahepatic bile ducts according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The therapeutic indication to be assessed was restricted by the requesting hospital to neoplasms not treatable by surgery. The assessment documents were transferred to IQWiG on 19 December 2016.

According to the requesting hospital, USgHIFU for primary malignant neoplasms of the liver and intrahepatic bile ducts represents a non-invasive treatment option for unresectable liver tumours, especially if these are in the vicinity of blood vessels and/or are larger than 5 cm.

For the assessment of USgHIFU for primary liver tumours, results from 2 comparative studies on hepatocellular carcinoma (HCC) were available for the outcomes of overall survival and adverse events.

Overall, the studies indicate positive effects of

- transarterial chemoembolization (TACE) + USgHIFU versus TACE alone
- USgHIFU + potentially TACE versus TACE alone

Both comparisons refer to patients with up to 4 HCC lesions, for whom neither transplantation nor radiofrequency ablation (RFA) is possible and who have neither massive ascites nor Child-Pugh class C cirrhosis.

Hence, on the basis of the assessment documents submitted, a potential of a required treatment alternative can be inferred for USgHIFU in 2 treatment strategies versus TACE alone in patients with unresectable HCC and the characteristics named above, which is particularly based on the available findings on overall survival. No statistically significant difference, or an evidently minor difference, was shown between both treatment arms with regard to adverse events.

In contrast, in the treatment of HCC it could not be determined that USgHIFU possesses the potential to replace other loco-regional procedures. Likewise, in the further indications provided by the requesting hospital (intrahepatic bile duct carcinoma, hepatoblastoma, angiosarcoma, as well as other tumours of the liver), none of the studies presented by the requesting hospital were suited to provide information on the potential or benefit of the method requested.

A testing study suited to obtain the necessary information for the assessment of the method's benefit is basically possible.

*The full report (German version) is published under <https://www.iqwig.de/en/projects-results/projects/non-drug-interventions/h16-02d-ultrasound-guided-high-intensity-focused-ultrasound-for-malignant-neoplasms-of-the-liver-and-the-intrahepatic-bile-ducts-assessment-according-to-137h-social-code-book-v.7718.html>.*