

IQWiG Reports – Commission No. H17-01

**Ultrasound-guided high-
intensity focused ultrasound
therapy for uterine fibroids
Addendum to Commission H16-02B¹**

Executive Summary

¹Translation of the executive summary of the addendum *Sonografiegesteuerte hochfokussierte Ultraschalltherapie beim Leiomyom des Uterus - Addendum zum Auftrag H16-02B* (Version 1.0; Status: 15 May 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

With its letter of 17 March 2017, for Commission H16-02B, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to systematically evaluate the assessment result according to §137h Social Code Book (SGB) V of the method “ultrasound-guided high-intensity focused ultrasound (USgHIFU) therapy for uterine fibroids”.

Research question

The aim of this examination according to the commissioning by the G-BA was to determine with regard to USgHIFU therapy for uterine fibroids whether, besides the documents already used in the §137h assessment H16-02B, further relevant studies or documents on relevant studies exist. If this was the case, it was to be examined whether, under their consideration, the present examination or treatment method still offers a potential or whether its benefit can already be considered to be sufficiently proven according to § 137h (1) Sentence 4 SGB V. Furthermore, it was to be evaluated whether, besides the studies already considered in the §137h assessment, there are any further ongoing studies that in principle are suited to provide relevant findings on the benefit of the method in the near future.

Methods

Documents on studies fulfilling the following criteria were included: randomized controlled trials (RCTs) and clearly prospectively planned intervention studies with concurrent control groups that took potential structural inequality of the groups under observation into account in the study planning and analysis, examined USgHIFU with regard to patient-relevant outcomes, and had not already been considered within the assessment according to §137h.

A systematic literature search for primary studies 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. In expectation of the commission, the search was conducted on 3 February 2017. In addition, systematic reviews and publicly available study registries were searched. The selection of relevant studies was performed by 2 reviewers independently of one another.

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

Results

The systematic literature search identified one additional completed RCT for which, however, no results were available. Moreover, one additional ongoing RCT was identified. This does not change the estimation that in patients with uterine fibroids, USgHIFU has the potential of

a required treatment alternative, but that its benefit cannot be regarded as sufficiently proven according to §137h (1) Sentence 4 SGB V.

Conclusion

After a systematic evaluation, USgHIFU still has a potential for uterine fibroids and its benefit cannot be regarded as sufficiently proven according to §137h (1) Sentence 4 SGB V. Beyond those studies already considered in the § 137h assessment H16-02B, one additional completed study was found for which, however, no results were available. Moreover, one additional ongoing study was identified for which it currently cannot conclusively be assessed whether and when it will provide relevant findings on the research question posed.

The full report (German version) is published under

<https://www.iqwig.de/en/projects-results/projects/non-drug-interventions/h-projekte/h17-01-ultrasound-guided-high-intensity-focused-ultrasound-for-uterine-fibroids-addendum-to-commission-h16-02b.7858.html>.