

IQWiG Reports – Commission No. E14-14

**Magnetic resonance  
imaging-guided high-intensity  
focused ultrasound therapy  
for uterine fibroids  
(addendum to commissions  
E14-04 and E14-05)<sup>1</sup>**

**Executive Summary**

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<sup>1</sup> Translation of the executive summary of the addendum to the assessment of potential *Magnetresonanztomografie-gesteuerte hochfokussierte Ultraschalltherapie zur Behandlung des Uterusmyoms (Addendum zu den Aufträgen E14-04 und E14-05)* (Version 2.0; Status: 10 March 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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<sup>2</sup> Due to legal data protection regulations, employees have the right not to be named.

## Executive summary

With its letter of 18 December 2104, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) with a supplementary assessment of commissions E14-04 and E14-05 in order to evaluate the conclusions on the potential (in terms of §137e Social Code Book V) of the method of magnetic resonance imaging guided high-intensity focused ultrasound (MRIg-HIFU) therapy for uterine fibroids (also called leiomyomas or myomas). The assessment (version 1.0) was completed on 11 March 2015 and transferred to the G-BA. As this version contained information that is protected by the administrative procedure, the present version 2.0 was prepared for publication, which does not contain this information. These changes in the presentation do not affect the result of the assessment.

## Research question

The subject of the assessment was to evaluate the conclusions on the potential of MRIg-HIFU under consideration of additional studies that the G-BA had transferred to IQWiG. The present examination thus aimed to determine whether the documents transferred by the G-BA contained relevant studies or study information. If this was the case, it was to be assessed whether, under their consideration, the present examination or treatment method offers sufficient potential. Furthermore, it was to be evaluated whether ongoing studies were named that in principle are suited to demonstrate a benefit in the near future.

If in the event of a potential of the method a testing study seemed necessary, ultimately the key points of such a study, together with its prospects of success, were to be characterized.

The evaluation of the potential of the method of MRIg-HIFU was especially performed for the following research questions:

- whether clinical effectiveness is recognizable for the method (research question 1)
- whether, with regard to invasiveness, the method possesses potential patient-relevant advantages over control interventions (research question 2)
- whether, with regard to fertility, the method possesses potential patient-relevant advantages over control interventions (research question 3)

## Methods

Those studies were included that corresponded at least to evidence level IV of the G-BA and contained relevant data on the research questions. Likewise, reviews were included that were based on a systematic search und included relevant data on the research questions.

The G-BA transferred the documents, the relevance of which was evaluated for each research question. No bibliographic literature search in addition to this or a search in study registries was conducted.

Furthermore, the studies presented by the applicants within the framework of the testing application were evaluated with regard to whether they were relevant for the research questions together with the studies additionally transferred.

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

## Results

In addition to the studies submitted within the framework of the testing application, 7 publications of the documents submitted contained relevant data for research question 1, 5 publications for research question 2, and 6 publications for research question 3.

The documents transferred, together with the documents originally submitted, overall indicate that the method of MRIg-HIFU is clinically effective. Furthermore, they indicate advantages over the comparator interventions (uterine artery embolization and myomectomy) with regard to the outcomes of length of hospital stay and time to return to normal activities. In contrast, a possible advantage of MRIg-HIFU in the area of fertility could not be recognized on the basis of the available documents.

No additional ongoing studies were named in the documents that were in principle suited to demonstrate a benefit of the method in the near future.

## Conclusion

Under consideration of the documents transferred within the framework of the application for testing as well as additionally transferred by the G-BA, a potential can be derived for the method of MRIg-HIFU therapy for the treatment of uterine fibroids.

A testing study that is 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/e14-14-magnetic-resonance-imaging-guided-high-intensity-focused-ultrasound-therapy-for-uterine-fibroids-addendum-to-commissions-e14-04-and-e14-05.7817.html>.*