

IQWiG Reports – Commission No. H16-02B

Ultrasound-guided high- intensity focused ultrasound therapy for uterine fibroids¹

Executive Summary

¹ Translation of the executive summary of the assessment according to § 137h Social Code Book (SGB) V *Sonografiegesteuerte hochfokussierte Ultraschalltherapie beim Leiomyom des Uterus* (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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² Due to legal data protection regulations, employees have the right not to be named.

Executive summary

The Federal Joint Committee commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess ultrasound-guided high-intensity focused ultrasound therapy (USgHIFU) for uterine fibroids according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The assessment documents were transferred to IQWiG on 19 December 2016.

According to the requesting hospital, the method aims to destroy the tumour tissue in patients with symptomatic uterine fibroids (also called myomas or leiomyomas).

For the assessment of USgHIFU for uterine fibroids, results from 1 randomized controlled trial (RCT) comparing USgHIFU versus open surgical myomectomy were available for the following outcomes: length of hospital stay, time to return to normal activities, and adverse events. For the comparison of USgHIFU versus laparoscopic myomectomy, results from 1 non-RCT were available for the outcomes of symptom severity, health-related quality of life, length of hospital stay, time to return to normal activities, and adverse events.

Overall, the studies indicate positive effects of USgHIFU regarding the outcomes of length of hospital stay and time to return to normal activities, without a relevant inferiority regarding quality-of-life and symptom-related outcomes being recognizable.

Hence, on the basis of the assessment documents submitted, a potential of a required treatment alternative can be inferred for USgHIFU versus open surgical or laparoscopic myomectomy in patients with uterine fibroids. This potential arises from the available findings on the outcomes of length of hospital stay and time to return to normal activities.

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/h16-02b-ultrasound-guided-high-intensity-focused-ultrasound-for-uterine-fibroids-assessment-according-to-137h-social-code-book-v.7716.html>.