

IQWiG Reports - Commission No. H21-14

Transcervical radiofrequency ablation with intrauterine ultrasound guidance for uterine fibroids¹

Extract

¹ Translation of the executive summary of the §137h assessment: H21-14 *Transzervikale Radiofrequenzablation mit intrauteriner Ultraschallführung bei Uterusmyomen* (Version 1.0; Status: 24 January 2022). 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 advisor for his contribution to the §137h assessment. However, the advisor was not involved in the preparation of the §137h assessment. IQWiG is solely responsible for the content of the §137h assessment.

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Executive summary

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the method "transcervical radiofrequency ablation with intrauterine ultrasound guidance for uterine fibroids (TRFA)" according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The assessment documents were submitted to IQWiG on 13 December 2021.

According to the information in the submission form, TRFA is used to treat symptomatic uterine fibroids, especially with regard to heavy bleeding and pain. Submucosal, intramural, subserosal or transmural fibroids are localized using an intrauterine ultrasound probe and ablated transcervically using radiofrequency energy.

Results from 5 case series were available for the assessment of TRFA. In addition, 1 randomized controlled trial (RCT) in the planning stage was mentioned.

No findings on the benefit, ineffectiveness and harmfulness of TRFA could be derived from the data submitted, as no comparative data were available. The supplementary examination of the results of the case series also did not indicate harmfulness of the method.

Overall, based on the submitted documents, neither a benefit, harmfulness or ineffectiveness of TRFA for patients with uterine fibroids can be identified in the present assessment according to §137h.

In order to gain the necessary knowledge on the possible benefit of TRFA, 2 medium-sized testing studies are necessary. This is because different control interventions are relevant depending on the location of the fibroids: In one RCT, women with subserosal, intra- or transmural fibroids should receive either TRFA or laparoscopic (possibly also combined laparoscopic-hysteroscopic) myomectomy. In the second study, submucosal fibroids should be treated either by TRFA or hysteroscopic myomectomy.

The full report (German version) is published under

https://www.iqwig.de/projekte/h21-14.html