IQWiG Reports – Commission No. H20-05

Transcranial magnetic resonance-guided focused ultrasound (tcMRgFUS) for the treatment of essential tremor[1]

Extract

[1] Translation of the executive summary of the §137h assessment: H20-05 *Transkranialer Magnetresonanz-gesteuerter fokussierter Ultraschall (TK-MRgFUS) zur Behandlung des essenziellen Tremors* (Version 1.1; Status: 22 February 2021). 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 expert 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 "transcranial magnetic resonance-guided focused ultrasound (tcMRgFUS) for the treatment of essential tremor" according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The assessment documents were submitted to IQWiG on 28 December 2020.

According to the information in the submission form, tcMRgFUS for the treatment of essential tremor is intended for the treatment of drug-refractory essential tremor in patients in whom unilateral treatment is sufficient. A distinction should be made between patients who are not or not yet eligible for deep brain stimulation (DBS) (Population A) and patients who are eligible for DBS (Population B). While in Population B, the comparison between tcMRgFUS and DBS is relevant, in Population A, the aim is to assess whether treatment using tcMRgFUS offers advantages as an additional intervention versus conservative treatment alone.

Population A

One randomized controlled trial (RCT) was used for the assessment of tcMRgFUS versus conservative treatment alone. In this RCT, tcMRgFUS was compared with sham treatment (i.e. no treatment). Both data from the randomized comparison and data on the subsequent follow-up of patients treated with tcMRgFUS outside the randomized comparison were considered. Overall, the results show an advantage of tcMRgFUS with respect to the outcomes of tremor, activities of daily living, global clinical assessment, and health-related quality of life. TcMRgFUS-related adverse events occurred, but did not outweigh the advantages.

Thus, based on the assessment documents submitted, a benefit of tcMRgFUS versus conservative treatment alone can be identified.

Population B

No RCTs were available to assess tcMRgFUS versus DBS. On the basis of 1 study with unadjusted indirect comparisons and 2 retrospective comparative cohort studies, no differences of a magnitude that could not be explained by systematic bias alone were apparent between tcMRgFUS and DBS with regard to the reported outcomes of tremor, activities of daily living, global clinical assessment, and adverse events. Likewise, an equivalence of tcMRgFUS to DBS cannot be inferred with sufficient certainty from these studies and their results.

In addition, the results that were primarily attributed to Population A can also be applied to Population B to a limited extent. This indicates that also in Population B, tcMRgFUS is neither harmful nor ineffective.

Overall, based on the documents submitted for tcMRgFUS in Population B, neither a benefit versus DBS nor harmfulness nor ineffectiveness of the method can be identified.

A testing study suitable to provide the necessary evidence to assess the benefit of the requested method versus DBS is possible in principle. However, such a study would only be able to recruit a much smaller number of patients than actually desirable (primarily due to the very small number of study centres expected). The additional use of a disease registry would be helpful.

The full report (German version) is published under

https://www.iqwig.de/en/projects/h20-05.html