MRI-guided high-intensity focused ultrasound therapy for uterine fibroids has potential

March 22 2017

For the first time since the corresponding law became effective in 2012, the German Institute for Quality and Efficiency in Health Care (IQWiG) has published an assessment of the potential of a new treatment method according to §137e of Social Code Book (SGB) V. The topic of the assessment of potential is the magnetic resonance imaging (MRI)-guided high-intensity focused ultrasound therapy for the treatment of uterine fibroids (also called leiomyomas or myomas).

Benign tissue nodules in the uterus are often accompanied by pain or cramps and stronger monthly periods. Conventional treatment comprises arterial embolization or surgical removal of the fibroid (myomectomy) or the uterus (hysterectomy). However, fibroids can also be heated by an ultrasound impulse directly focused on the respective fibroid and can thus be destroyed. In this context, focusing is monitored by MRI.

In comparison with other interventions, this new method has the potential to reduce the length of hospital stays and accelerate the resumption of normal activities. According to IQWiG, a testing study to obtain the necessary information for a benefit assessment is possible.

Identical applications - identical assessments of potential

The so-called testing regulation (§137e SGB V) was introduced with the

German Structure of Health Care Act (GKV-VStG) of 2012: The Federal Joint Committee (G-BA) can decide on directives for the testing of examination and treatment methods whose benefit has not yet been sufficiently proven, but that indicate "the potential of a required treatment alternative". This gives the G-BA the opportunity to initiate clinical studies and thus improve the evidence base.

In April 2014 the G-BA awarded 2 commissions to IQWiG that referred to the same method whose potential was to undergo assessment at the request of not just 1 but 2 applicants. In its 2 assessments of potential (E14-04 und E14-05) of identical content, the Institute could not initially infer a potential from the documents submitted: Due to a lack of comparative study data, it was not recognizable whether the new method possibly offers advantages for patients because it is less invasive and whether it is more effective at all than placebo or no treatment.

Assessment process over nearly 3 years

In December 2014 the G-BA transferred new information to the Institute within the framework of a new commission. On this basis, in addendum E14-14 IQWiG attributed a potential to the method and outlined the key points and prospects of success of a testing study. Subsequently, in June 2015, the G-BA commissioned the Institute to evaluate whether further ongoing or already completed studies existed that were not named in the documents and would render a testing study obsolete. According to addendum E15-02 this is not the case.

On the basis of these 4 assessments, in December 2016 the G-BA decided on a testing directive, so that henceforth the course is set for a testing study on MRI-guided high-intensity focused ultrasound therapy for the treatment of uterine fibroids. In particular this study should clarify whether the method is clinically effective and whether it offers patients advantages with regard to invasiveness and fertility. On 8 March

2017 the G-BA's decision was published in the German Federal Gazette. Only afterwards was IQWiG able to publish the corresponding assessments of potential and addenda.

Most assessments of potential are not published

So far IQWiG has conducted 17 assessments of the potential of new methods according to §137e SGB V. However, only those methods are made public for which the G-BA has initiated consultation procedures to prepare testing directives. A total of 15 of IQWiG's reports have not yet been published. Jürgen Windeler, IQWiG's Director, comments on this particularity: "This doesn't quite fit the Institute's principles. At IQWiG, the transparency of working methods, procedures and results is a top priority: Good scientific practice means that others are able to follow and critically evaluate our work. But our assessments of potential are part of an administrative procedure supervised by the G-BA and for this reason, even within the Institute, are only allowed to be disclosed to those directly involved. We are only allowed to publish them if the G-BA decides on a testing directive."

Reasons for non-realization are left in the dark

The IQWiG Director further states: "Even if IQWiG concluded that a method could cause major harm to patients, we would not be allowed to publish our report. At any rate, it remains unclear to the public which methods we investigated in the course of §137e and why a testing study was not initiated - because we did not attribute a potential to the method, or because studies are already being conducted that could provide information on benefit, or because the applicants were not prepared to contribute to the costs."

According to §137e, the willingness to contribute to the costs for a

testing study is a further prerequisite for a G-BA testing directive. But this is not always in the commercial interest of the provider, and thus some potentially beneficial methods remain untested.

Provided by Institute for Quality and Efficiency in Health Care