

High-risk medical devices: IQWiG sees no potential in 6 of 8 cases

March 22 2017

The German Institute for Quality and Efficiency in Health Care (IQWiG) has completed 8 assessments of the benefit and potential of new treatment methods with high-risk class medical devices. Besides targeted lung denervation in patients with chronic obstructive pulmonary disease (COPD), a further method was investigated for 7 other indications: Ultrasound-guided high-intensity focused ultrasound (USgHIFU) is to be used to treat uterine endometriosis and fibroids, as well as pancreatic tumours, primary and secondary liver tumours, and primary and secondary bone malignancies if patients are not eligible for surgery.

The Institute could only recognize a so-called "potential of a required treatment alternative" for 2 therapeutic indications, namely uterine fibroids and primary liver tumours. No potential could be inferred for the other 6 indications from the documents submitted.

"Potential of a required treatment alternative" investigated

The assessment of new treatment methods largely based on high-risk class medical devices was introduced in 2015 with the German Statutory Health Insurance Act to Promote Health Care (GKV-VSG) as §137h in Social Code Book (SGB) V. In 2016 it was specified by corresponding rules of procedure of the Federal Joint Committee (G-BA).

This assessment procedure is triggered by a hospital submitting a request for additional compensation for the remuneration of healthcare services to the Institute for the Fee System in the Hospital (InEK). Such a request for a new examination and treatment [method](#) is called an "NUB request" ("Neue Untersuchungs- und Behandlungsmethoden"). Together with the NUB request, the hospital also submits the available scientific evidence on the new method to the G-BA.

If the method is largely based on the use of high-risk class medical devices and represents a new theoretical-scientific concept, the G-BA must determine if the benefit of the method is proven or whether it at least "offers the potential of a required treatment alternative". This means that patients might possibly get well faster or the new method might be less burdensome than those methods currently available. For this purpose, the G-BA commissions IQWiG to assess the scientific evidence submitted by the hospital.

Questionable applicability of results between indications

From IQWiG's point of view, a potential resulting from the documents on an indication cannot necessarily be applied to other indications where the same method is used. For example, liver tumours are something completely different from benign uterine growths or malignant bone tumours. Ultrasound therapy that can destroy a growth in one indication without damaging the adjacent tissue could be ineffective in another indication or cause harm.

Plausibility alone is insufficient

Likewise, a plausible mode of action is insufficient to attribute a potential to the method. According to the explanation of the law "a

potential for the necessity of a method can, for example, arise from the fact that, because of its mode of action and the evidence so far available, it is associated with the expectation that it can replace other methods that are more elaborate and more invasive for patients or unsuccessful in certain patients."

Sparse information

Such evidence is available for both indications where IQWiG sees a potential. Positive results on the treatment of [uterine fibroids](#) were available from a non-randomized and a randomized controlled trial; 2 comparative studies on primary liver cancer also indicated positive effects. In both cases, a testing study is basically possible to obtain the necessary information for a benefit assessment.

In contrast, for the other 6 indications, the evidence submitted largely consisted of case series that provided hardly any information on the potential benefit or harm of the methods - especially as no data were submitted on the course of disease without the new method. For one indication, no data were provided at all.

"Obligation to deliver" instead of "obligation to collect"

In assessments according to §137h, IQWiG itself does not search for study data; rather, the requesting hospitals must demonstrate that a potential exists by means of comprehensible data. The Institute's Director Jürgen Windeler emphasizes: "If they do that, their chances are good. The 2 cases in which we attributed a potential to ultrasound-guided high-intensity focused ultrasound show that one can also reach a preliminary positive result on the basis of a few studies - even if the data are insufficient to already consider the benefit to be proven. However, it

is out of the question that, to provide a first evaluation of such methods, the Institute has an "obligation to collect" and may possibly have to exhaustively search the international literature to prove that a method has no potential."

Was does evidence-based medicine mean and what is its purpose?

Jürgen Windeler is concerned that only sparse evidence is available for methods that evidently are already being used in [health care](#): "Apparently one must again and again justify the standards of evidence-based medicine, otherwise they are called into question as being detrimental to innovation. We do not insist on well planned, properly conducted, sufficiently large, transparently documented, low risk-of-bias studies because of bureaucratic nitpicking: The benefit and harm for patients simply cannot be assessed in any other way - and we are not talking about plasters and nappies here, but about high-risk devices where nerves are clipped irreversibly or organs are treated with very high-energy ultrasound."

Provided by Institute for Quality and Efficiency in Health Care

Citation: High-risk medical devices: IQWiG sees no potential in 6 of 8 cases (2017, March 22) retrieved 5 May 2024 from <https://medicalxpress.com/news/2017-03-high-risk-medical-devices-iqwig-potential.html>

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