IQWiG Reports – Commission No. H18-02

Targeted lung denervation using catheter ablation for chronic obstructive pulmonary disease – Addendum to Commission H16-01[1]

Extract

[1] Translation of the executive summary of addendum H18-02 *Gezielte Lungendenervierung durch Katheterablation bei chronisch obstruktiver Lungenerkrankung – Addendum zum Auftrag H16-01* (Version 1.0; Status: 27 April 2018). Please note: This document was translated by an external translator and 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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Executive summary

On 22 March 2018, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to generate an addendum to commission H16-01.

On the basis of the document sent by the G-BA on the method "Targeted lung denervation by catheter ablation in chronic obstructive lung disease" (COPD), this assessment aimed to re-evaluate whether the method shows a benefit or potential in accordance with Section 137h SGB V. According to the manufacturer, targeted lung denervation (TLD) is intended for patients with moderate to severe COPD who remain symptomatic despite receiving optimal medical care.

This assessment was primarily based on additional study results that the G-BA sent to IQWiG at the time it commissioned the addendum. The G-BA received them from the manufacturer of the medical device. The assessment by IQWiG followed the methodology used in the original Sect. 137h assessment based on the principles described in the Institute's method paper. The responsibility for this assessment and the assessment results lies exclusively with IQWiG.

The document sent by G-BA contains a summary of results of the AIRFLOW-2 trial, which was already known to exist when assessment H16-01 was generated, but no results were available at that time. In addition to the document sent, supplementary information from other documents submitted in connection with assessment H16-01 was used.

The AIRFLOW-2 trial used a randomized, double-blind design to study the use of TLD in comparison with a sham control. In both arms of the trial, patients received standardized add-on treatment with tiotropium as the sole LAMA (long-acting muscarinic antagonist, anti-cholinergic), and for most outcomes, an analysis was performed 6 months after treatment. Then tiotropium treatment was interrupted for at least 1 week, and 6.5 months after therapy, another analysis was performed for TLD therapy without add-on tiotropium treatment. For this assessment, we used only the results on TLD therapy with tiotropium that were analyzed at the 6-month point post therapy (quality of life, severity of dyspnea, exercise capacity) or for the period from 3 to 6.5 months post therapy (respiratory adverse events [respiratory AEs]) and from treatment to 6.5 months thereafter (serious adverse events [SAEs]).

The trial suggests positive effects of TLD for the outcomes respiratory AEs (primary outcome) and severity of dyspnea; this applies at least until 6.5 months post treatment. No data were available (yet) for the later times of evaluation. No statistically significant difference between treatment arms was found for the outcomes health-related quality of life, exercise capacity, and SAEs.

On the basis of the submitted documents, a potential of add-on TLD (TLD + LAMA) in chronic obstructive pulmonary disease can therefore be derived when compared to LAMA medication; this potential is based primarily on the available information regarding the outcomes respiratory AEs and severity of dyspnea (measured by the Transition Dyspnea Index, TDI).

It is generally possible to conduct a testing study that is suitable for collecting the information necessary for assessing the benefit of the method.

The full report (German version) is published under https://www.iqwig.de/de/projekte-ergebnisse/projekte/nichtmedikamentoese-verfahren/h-projekte/h18-02-gezielte-lungendenervierung-durch-katheterablation-bei-chronisch-obstruktiver-lungenerkrankung-addendum-zum-auftrag-h16-01.8861.html