



IQWiG Reports – Commission No. H21-11

Drug-coated balloon catheter for the transurethral treatment of urethral strictures

2. Addendum to Commission H20-02¹

Extract

¹ Translation of the executive summary of the addendum H21-11 *Medikamentenbeschichteter Ballondilatationskatheter zur transurethralen Behandlung von Harnröhrenstrikturen – 2. Addendum zum Auftrag H20-02* (Version 1.0; Status: 30 August 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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Executive summary

In a letter dated 26 August 2021, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG), as an addendum to commission H20-02, to evaluate the documents on an ongoing and a planned study submitted during the commenting procedure. The aim was to determine whether there are any new findings for the consultation procedure on a directive on the testing of the method “drug-coated balloon catheter” (hereafter: urethral DCB) for the transurethral treatment of urethral strictures.

Research question

The aim of the present investigation was to evaluate the documents on an ongoing and a planned study submitted during the commenting procedure to see whether they provide new findings for the consultation procedure on urethral DCB, in particular with regard to the suitability of the two studies to generate data on the benefit of the method; this would make a testing study obsolete.

Conclusion

According to the current state of knowledge, the planned ReBUS study would in principle be suitable for providing evidence of the benefit, ineffectiveness or harmfulness of the method to be assessed; however, the funding planned and thus the implementation of this study is questionable. The ROBUST-III study is very probably not suitable to gain the necessary knowledge for the assessment of the benefit of the method to be assessed. If the ReBUS study is not conducted, it will still be necessary to conduct a separate testing study.

The full report (German version) is published under

<https://www.iqwig.de/projekte/h21-11.html>