

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

Third addendum to Project H20-02¹

A decorative horizontal bar composed of 20 squares of varying shades of blue and grey. The word 'EXTRACT' is centered in a dark blue rectangle that spans the width of the bar.

EXTRACT

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¹ Translation of the executive summary of the addendum H23-02 *Medikamentenbeschichteter Ballondilatationskatheter zur transurethralen Behandlung von Harnröhrenstrikturen - 3. Addendum zum Auftrag H20-02* (Version 1.0; Status: 18 April 2023). 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 23 February 2023, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to re-investigate the drug-coated balloon dilatation catheter (hereinafter: urethral DCB) for the treatment of urethral strictures as an addendum to Commission H20-02. It is questionable whether the ROBUST-III study appears suitable for demonstrating the benefit of urethral DCB.

Research question

The aim of the present investigation was to analyse the meanwhile published 1-year data of the ROBUST-III study and the other documents related to the study, which were made available to the G-BA, to determine whether the ROBUST-III study data appear suitable for gaining the necessary findings for the assessment of the benefit of urethral DCBs, which would render a testing study obsolete.

Conclusion

The ROBUST-III study is not suitable for gaining the necessary findings to assess the benefit of the requested method. This applies both to the overall data on the comparison of urethral DCB versus endourological procedures and to the relevant comparison of urethral DCB versus internal urethrotomy. If the ReBUS study is not conducted, it will therefore be necessary to conduct a separate testing study.

*The full report (German version) is published under
<https://www.iqwig.de/en/projects/h23-02.html>*