



IQWiG Reports – Commission No. H21-03

**Drug-coated balloon catheter  
for the transurethral treatment  
of urethral strictures  
Addendum to commission H20-02<sup>1</sup>**

**Extract**

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<sup>1</sup> Translation of the executive summary of the addendum H21-03: *Medikamentenbeschichteter Ballondilatationskatheter zur transurethralen Behandlung von Harnröhrenstrikturen – Addendum zum Auftrag H21-03* (Version 1.0; Status: 12 May 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 6 April 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 examine the conclusions of the assessment according to §137h Social Code Book (SGB) V on the benefit, harmfulness and ineffectiveness of the method “drug-coated balloon catheter for the transurethral treatment of urethral strictures” (in the following: urethral DCB).

## ***Research question***

The aim of the present investigation was to determine whether further relevant studies on urethral DCB for the transurethral treatment of urethral strictures exist besides the documents already used in the §137h assessment H20-02. If this was the case, it was to be examined whether, taking these into account, neither a benefit, harmfulness nor ineffectiveness could be identified for the examination or treatment method in question. Furthermore, it was to be examined whether, besides the studies already used in the §137h assessment, ongoing studies exist that are in principle suitable to provide relevant findings on the benefit, harmfulness or ineffectiveness of the method in the near future.

## ***Methods***

Randomized controlled trials (RCTs) were to be included that investigated urethral DCB for the transurethral treatment of urethral strictures with regard to patient-relevant outcomes and had not already been used in the assessment according to §137h.

A systematic literature search for studies was conducted in MEDLINE, Embase, and the Cochrane Central Register of Controlled Trials. In parallel, a search for relevant systematic reviews was conducted in MEDLINE, Embase, the Cochrane Database of Systematic Reviews, and the HTA Database. The search was conducted on 12 April 2021. In addition, the following information sources and search techniques were considered: study registries and screening of reference lists. The selection of relevant studies was performed by 2 reviewers independently of one another.

## ***Results***

No additional relevant completed or ongoing studies related to the present research question were identified in the information retrieval process. Moreover, there is no new information on the currently ongoing RCT ROBUST-III (NCT03499964) and we refer to the §137h assessment H20-02.

## ***Conclusion***

After systematic examination, there is still no evidence of a benefit, ineffectiveness or harmfulness of urethral DCB for the transurethral treatment of urethral strictures. Beyond the studies already considered in the §137h assessment, no additional completed or ongoing studies were found that would in principle be suitable to provide evidence of a benefit, ineffectiveness or harmfulness in the near future.

The full report (German version) is published under  
<https://www.iqwig.de/en/projects/h21-03.html>