IQWiG Reports – Commission No. H20-02

Drug-coated balloon catheter for the transurethral treatment of urethral strictures[1]

Extract

[1] Translation of the executive summary of the §137h assessment: H20-02 *Medikamentenbeschichteter Ballondilatationskatheter zur transurethralen Behandlung von Harnröhrenstrikturen* (Version 1.1; Status: 12 February 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.

Publishing details

Publisher
Institute for Quality and Efficiency in Health Care

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

Commissioning agency
Federal Joint Committee

Commission awarded on
16 December 2020

Internal Commission No.
H20-02

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IQWiG thanks the medical expert advisor for his contribution to the §137h assessment. However, the advisor was not involved in the preparation of the §137h assessment. IQWiG is solely responsible for the content of the §137h assessment.

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Keywords: Drug-Coated Balloon, Dilatation, Paclitaxel, Urethral Stricture, Device Approval, Risk Assessment, Benefit Assessment

Executive summary

The Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the method "drug-coated balloon catheter for the transurethral treatment of urethral strictures" (urethral DCB) according to §137h Social Code Book (SGB) V – Statutory Health Insurance. The assessment documents were submitted to IQWiG on 17 December 2020.

According to the information in the submission form, urethral DCB is intended to treat symptomatic recurrent strictures in the anterior urethra in men. This includes both single strictures up to 2 cm in length that are currently treated primarily by urethrotomia interna (Population A) as well as radiogenically induced urethral strictures that are currently treated by urethroplasty (Population B). Urethral DCB can be used alone or in combination with other endourological procedures.

A total of 3 studies were available for the assessment of the method requested. Among them were 2 case series (1-arm observational studies, ROBUST-I and ROBUST-II) with results, of which 1 (ROBUST-II) did not correspond to the population requested. Results were not yet available for 1 randomized controlled trial (RCT), ROBUST-III.

For Population A, no findings on the benefit, ineffectiveness or harmfulness of urethral DCB could be derived from the data submitted, as no comparative data were available. Likewise, the supplemental examination of the results of the case series (ROBUST-I) did not suggest that the method is harmful. From a medical point of view, it seems plausible to assume that this evaluation can also be applied to Population B.

Overall, in this assessment according to §137h, based on the documents submitted for urethral DCB in the two medical indications, neither a benefit, harmfulness nor ineffectiveness can be identified.

A testing study suitable to provide the necessary findings to assess the benefit of the method is possible in principle.

For Population A, such a study is already being conducted abroad (ROBUST-III). However, since it is currently unclear whether it is actually suitable to demonstrate the benefit of urethral DCB in this medical indication, key points of a testing study in Germany are outlined. To demonstrate the superiority of urethral DCB versus urethrotomia interna in terms of the stricture-free rate, a medium-sized RCT with 100 to < 500 patients with symptomatic short-segment (≤ 2 cm) recurrent stricture of the anterior urethra is required.

Because of the low invasiveness of urethral DCB versus urethroplasty with a graft, demonstration of non-inferiority in terms of the stricture-free rate is sufficient. For this, a medium-sized RCT of 100 to < 500 patients with symptomatic, short-segment (≤ 2 cm), radiogenically induced recurrent stricture of the anterior urethra is required.

The full report (German version) is published under

https://www.iqwig.de/en/projects/h20-02.html