



IQWiG Reports – Commission No. A18-22

# **Glycopyrronium bromide (sialorrhoea) –**

## **Benefit assessment according to §35a Social Code Book V<sup>1</sup>**

**Extract**

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<sup>1</sup> Translation of the executive summary of the dossier assessment *Glycopyrroniumbromid (Sialorrhö) – Nutzenbewertung gemäß § 35a SGB V* (Version 1.0; Status: 27 June 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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IQWiG thanks the medical and scientific advisor for his contribution to the dossier assessment. However, the advisor was not involved in the actual preparation of the dossier assessment. The responsibility for the contents of the dossier assessment lies solely with IQWiG.

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## Executive summary of the benefit assessment

### Background

In accordance with §36a Social Code Book (SBG) V, the Federal Joint Committee (G-BA) commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) to assess the benefit of the drug glycopyrronium bromide. The assessment was based on a dossier compiled by the pharmaceutical company (hereinafter referred to as the “company”). The dossier was sent to IQWiG on 29 March 2018.

### Research question

The aim of this report is to assess the added benefit of glycopyrronium bromide in comparison with best supportive care (BSC) as the appropriate comparator therapy (ACT) for the symptomatic treatment of severe sialorrhoea (chronic excess saliva production) in children and adolescents from the age of 3 years with chronic neurological disorders.

Table 2 presents the research question of the benefit assessment and the ACT specified by the G-BA.

Table 2<sup>2</sup>: Research question of the benefit assessment of glycopyrronium bromide

Research question	Indication	ACT <sup>a</sup>
1	Symptomatic treatment of severe sialorrhoea (chronic excess saliva production) in children and adolescents from the age of 3 years with chronic neurological disorders	Best supportive care (BSC) <sup>b</sup>

a: Presentation of the ACT specified by the G-BA  
b: BSC is defined as the treatment that ensures the best possible, individually optimized supportive care to alleviate symptoms and improve the quality of life. In Germany, no drugs are approved for the treatment of severe sialorrhoea or hypersalivation in children and adolescents from the age of 3 years. As part of BSC, therapies and therapeutic appliances, such as functional dysphagia therapy, should also be considered both in the intervention group and in the control group.  
ACT: appropriate comparator therapy; BSC: Best supportive care

The company followed the G-BA’s specification of the ACT (BSC).

The assessment was conducted by means of patient-relevant outcomes on the basis of the data provided by the company in the dossier.

### Results

For the assessment of the added benefit of glycopyrronium bromide in the symptomatic treatment of severe sialorrhoea in children and adolescents from the age of 3 years with chronic neurological disorders, the company presented 3 studies: 2 randomized controlled trials (RCTs) (Zeller 2012a and Mier 2000) which compare glycopyrronium bromide with placebo and

<sup>2</sup> Table numbers start with “2” as numbering follows that of the full dossier assessment.

1 single-arm trial (Zeller 2012b). None of the 3 studies used the ACT specified by the G-BA (BSC), although treatment options in line with the ACT, such as functional dysphagia therapy, exist. Hence, no added benefit can be derived from the studies presented by the company. The data presented by the company therefore resulted in no hint of added benefit of glycopyrronium bromide in comparison with the ACT (BSC); an added benefit is therefore not proven.

**Probability and extent of added benefit, patient groups with therapeutically important added benefit<sup>3</sup>**

On the basis of the results presented, the probability and extent of the added benefit of glycopyrronium bromide compared with the ACT is assessed as follows:

Table 3 presents a summary of the probability and extent of the added benefit of glycopyrronium bromide.

Table 3: Glycopyrronium bromide – probability and extent of added benefit

Indication	ACT <sup>a</sup>	Probability and extent of added benefit
Symptomatic treatment of severe sialorrhoea (chronic excess saliva production) in children and adolescents from the age of 3 years with chronic neurological disorders	Best supportive care (BSC) <sup>b</sup>	Added benefit not proven
a: Presentation of the respective ACT specified by the G-BA. b: BSC is considered the treatment that ensures the best possible, individually optimized supportive care to alleviate symptoms and improve the quality of life. In Germany, no drugs are approved for the treatment of severe sialorrhoea or hypersalivation in children and adolescents from the age of 3 years. As part of BSC, therapies and therapeutic appliances, such as functional dysphagia therapy, should also be considered both in the intervention group and in the control group. ACT: appropriate comparator therapy; BSC: Best supportive care; G-BA: Federal Joint Committee		

The G-BA decides on the added benefit.

<sup>3</sup> On the basis of the scientific data analysed, IQWiG draws conclusions on the (added) benefit or harm of an intervention for each patient-relevant outcome. Depending on the number of studies analysed, the certainty of their results, and the direction and statistical significance of treatment effects, conclusions on the probability of (added) benefit or harm are graded into 4 categories: (1) “proof”, (2) “indication”, (3) “hint”, or (4) none of the first 3 categories applies (i.e., no data available or conclusions 1 to 3 cannot be drawn from the available data). The extent of added benefit or harm is graded into 3 categories: (1) major, (2) considerable, (3) minor (in addition, 3 further categories may apply: non-quantifiable extent of added benefit, added benefit not proven, or less benefit). For further details see [1,2].

### References for English extract

Please see full dossier assessment for full reference list.

1. Institute for Quality and Efficiency in Health Care. General methods: version 5.0 [online]. 10 July 2017 [Accessed: 04 June 2018]. URL: [https://www.iqwig.de/download/General-Methods\\_Version-5-0.pdf](https://www.iqwig.de/download/General-Methods_Version-5-0.pdf).
2. Skipka G, Wieseler B, Kaiser T, Thomas S, Bender R, Windeler J et al. Methodological approach to determine minor, considerable, and major treatment effects in the early benefit assessment of new drugs. *Biom J* 2015; 58(1): 43-58

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