Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Glycopyrronium (severe primary axillary hyperhidrosis)

of 19 January 2023

At its session on 19 January 2023, the Federal Joint Committee (G-BA) resolved to amend the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), as last amended by the publication of the resolution of D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. Annex XII shall be amended in alphabetical order to include the active ingredient Glycopyrronium as follows:

Glycopyrronium

Resolution of: 19 January 2023
Entry into force on: 19 January 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 1 June 2022):

Axhidrox is used for topical treatment of severe primary axillary hyperhidrosis in adults.

Therapeutic indication of the resolution (resolution of 19 January 2023):

See therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

Adults with severe primary axillary hyperhidrosis

Appropriate comparator therapy for glycopyrronium (topical therapy):

- a formulation containing aluminium chloride (min. 15 %) or tap water iontophoresis

Extent and probability of the additional benefit of glycopyrronium compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:

Adults with severe primary axillary hyperhidrosis

There are no assessable data for the benefit assessment.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.c.	There are no assessable data.
Morbidity	n.c.	There are no assessable data.
Health-related quality of life	n.c.	There are no assessable data.
Side effects	n.c.	There are no assessable data.

Explanations:
↑ statistically significant and relevant positive effect with low/unclear reliability of data
↓ statistically significant and relevant negative effect with low/unclear reliability of data
↑↑ statistically significant and relevant positive effect with high reliability of data
↓↓ statistically significant and relevant negative effect with high reliability of data
↔: no statistically significant or relevant difference
∅: There are no usable data for the benefit assessment.
n.c.: not calculable

2. Number of patients or demarcation of patient groups eligible for treatment

Adults with severe primary axillary hyperhidrosis

approx. 73,000 to 704,000 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account.

4. Treatment costs

Annual treatment costs:

Adults with severe primary axillary hyperhidrosis

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed	
Glycopyrronium	€ 202.17 - € 707.51
appropriate comparator therapy[1]	
Tap water iontophoresis	incalculable

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 January 2023)

Costs for additionally required SHI services: not applicable

5. Medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with Glycopyrronium

Medicinal products with the following new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients that can be used in a combination therapy with glycopyrronium for the treatment of severe primary axillary hyperhidrosis on the basis of the marketing authorisation granted under Medicinal Products Act:

Adults with severe primary axillary hyperhidrosis

- *No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.*

1 The appropriate comparator therapy also includes pharmacy-only, non-prescription medicinal products (aluminium chloride-containing formulation). These are excluded from care according to Section 31 SGB V. An exceptional circumstance according to Section 34 paragraph 1 sentence 2 SGB V does not exist. Thus, the prescription of these medicinal products is not allowed at the expense of the statutory health insurance. Therefore, the cost illustration for these preparations is omitted in the resolution according to Section 35a paragraph 3 SGB V.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 January 2023.

The justification to this resolution will be published on the website of the G-BA at www.g-ba.de.

Berlin, 19 January 2023

Federal Joint Committee (G-BA)
in accordance with Section 91 SGB V
The Chair

Prof. Hecken