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 Olopatadine/ mometasone (allergic rhinitis, ≥ 12 years)

of 1 June 2023

At its session on 1 June 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 Olopatadine/ mometasone as follows:

Olopatadine/ mometasone

Resolution of: 1 June 2023
Entry into force on: 1 June 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 17 November 2021):

Ryaltris is indicated in adults and adolescents 12 years of age and older for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis.

Therapeutic indication of the resolution (resolution of 1 June 2023):

see therapeutic indication according to marketing authorisation.

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

Adults and adolescents aged 12 years and older with moderate to severe nasal symptoms associated with allergic rhinitis

Appropriate comparator therapy:

- Intranasal glucocorticoids (inGCS) in combination with intranasal antihistamine (INAH)

Extent and probability of the additional benefit of olopatadine/ mometasone compared to the appropriate comparator therapy:

An additional benefit is not proven.

Study results according to endpoints:[1]

Adults and adolescents aged 12 years and older with moderate to severe nasal symptoms associated with allergic rhinitis

There are no assessable data.

[1] Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A22-125) unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	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 ∅: No data available. n.a.: not assessable		

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

Adults and adolescents aged 12 years and older with moderate to severe nasal symptoms associated with allergic rhinitis

Approx. 3,807,000 to 7,356,000 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:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Olopatadine/ mometasone	€ 405.39
Appropriate comparator therapy:	

Designation of the therapy	Annual treatment costs/ patient
Intranasal glucocorticoids (inGCS) in combination with intranasal antihistamine (INAH)	€ 378.67 - € 442.38[2]

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 May 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 Olopatadine/ mometasone

Medicinal products with the 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 olopatadine/ mometasone for the treatment of moderate to severe nasal symptoms associated with allergic rhinitis in adolescents 12 years of age and older on the basis of the marketing authorisation granted under Medicinal Products Act:

<u>Adults and adolescents aged 12 years and older with moderate to severe nasal symptoms associated with allergic rhinitis</u>

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

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

[2] The range is made up of the less expensive combination therapy azelastine + budesonide and a more costly combination therapy levocabastine + budesonide.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 1 June 2023.

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

Berlin, 1 June 2023

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

Prof. Hecken