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) and Annex XIIa – Naming of Medicinal Products with New Active Ingredients according to Section 35a, paragraph 3, sentence 4 SGB V:
Beclometasone/ formoterol/ glycopyrronium (repeal of the resolution and repeal of the naming)

of 19 December 2024

At its session on 19 December 2024, 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 is amended as follows:

The findings on the benefit assessment of the fixed-dose combination of active ingredients beclometasone/ formoterol/ glycopyrronium in the new therapeutic indication according to the marketing authorisation of 14 January 2021 for the treatment of asthma in adult patients not adequately controlled with a combination of a long-acting beta2-agonist and medium dose or high dose of inhaled corticosteroid, and who experienced one or more asthma exacerbations in the previous year, in Annex XII of the Pharmaceuticals Directive in the version of the resolutions of 5 August 2021 (BAnz AT 11.10.2021 B1), and of 12 October 2021 (BAnz AT 17.12.2021 B4), are deleted.

II. Annex XIIa is amended as follows:

1. The information on the active ingredient benralizumab of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 2 August 2018) in the version of the resolution of 16 November 2023 (BAnz AT 05.02.2024 B5) is amended as follows:

In the patient groups a and b, the information "Formoterol/ glycopyrronium/ beclometasone (Trimbow)" is deleted after the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

2. The information on the active ingredient dupilumab of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 20 February 2020) in the version of the resolution of 16 November 2023 (BAnz AT 05.02.2024 B5) is amended as follows:

   In the patient group b, the information "Formoterol/ glycopyrronium/ beclometasone (Trimbow)" is deleted after the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

3. The information on the combination of active ingredients fluticasone/ vilanterol of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 2 August 2018) in the version of the resolution of 16 November 2023 (BAnz AT 05.02.2024 B5) is amended as follows:

   The information "Formoterol/ glycopyrronium/beclometasone (Trimbow)" after the heading "Period of validity of the naming (since... or from... to)" is deleted.

4. The information on the active ingredient mepolizumab of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 21 July 2016) in the version of the resolution of 16 November 2023 (BAnz AT 05.02.2024 B5) is amended as follows:

   In the patient groups a and b, the information "Formoterol/ glycopyrronium/ beclometasone (Trimbow)" is deleted after the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

5. The information on the active ingredient reslizumab of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 6 July 2017) in the version of the resolution of 16 November 2023 (BAnz AT 05.02.2024 B5) is amended as follows:

   In the patient groups a and b, the information "Formoterol/ glycopyrronium/ beclometasone (Trimbow)" is deleted after the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

6. The information on the active ingredient tezepelumab of the assessed medicinal product (resolution according to Section 35a paragraph 3 SGB V of 12 May 2023) in the version of the resolution of 21 December 2023 (BAnz AT 14.02.2024 B7) is amended as follows:

In the patient group b, the information "Formoterol/ glycopyrronium/ beclometasone (Trimbow)" is deleted after the heading "Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names[2])".

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 December 2024.

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

Berlin, 19 December 2024

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

Prof. Hecken