Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) 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:
Semaglutide (type 2 diabetes mellitus) (amendments to Annexes XII and XIIa)

of 20 March 2025

Contents

1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of all reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet. According to Section 35a paragraph 3 SGB V, the G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published on the internet and is part of the Pharmaceuticals Directive.

In accordance with Section 35a, paragraph 3, sentence 4 SGB V added to the Act on the Financial Stabilisation of Statutory Health Insurance (GKV-FinStG), which came into force on 8 November 2022, the G-BA names - in the resolution according to Section 35a paragraph 3 SGB V - all medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product for the therapeutic indication to be assessed on the basis of the marketing authorisation under Medicinal Products Act, unless the Federal Joint Committee has identified at least a considerable additional benefit of the combination pursuant to sentence 1 or has determined pursuant to paragraph 1d sentence 1 that the combination is expected to have at least a considerable additional benefit.

2. Key points of the resolution

The active ingredient semaglutide was first approved on 8 February 2018 as the active ingredient in the medicinal product Ozempic indicated for the treatment of adults with insufficiently controlled type 2 diabetes mellitus as an adjunct to diet and exercise

- as monotherapy when metformin is considered inappropriate due to intolerance or contraindications
- in addition to other medicinal products for the treatment of diabetes mellitus

and placed on the market on 1 November 2018. At their session on 2 May 2019 (BAnz AT 04.06.2019 B3), the G-BA decided on the benefit assessment of semaglutide in accordance with Section 35a SGB V and supplemented Annex XII with information on the active ingredient semaglutide in the therapeutic indication for the treatment of adults with insufficiently controlled type 2 diabetes mellitus. By resolution of 4 July 2019 (BAnz AT 12.09.2019 B3), this information under section "4. Treatment costs" of Annex XII was amended.

Following the marketing authorisation of the medicinal product Rybelsus with the same active ingredient semaglutide in the therapeutic indication for the treatment of adults with insufficiently controlled type 2 diabetes mellitus to improve glycaemic control as an adjunct to diet and exercise (monotherapy or combination therapy) on 3 April 2020, the G-BA, at the request of its members, initiated a benefit assessment by resolution of 16 April 2020 due to the presence of new scientific findings in accordance with Section 35a paragraph 1 SGB V in conjunction with Section 3, paragraph 1, no. 4 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) and Chapter 5 Section 13 Rules of Procedure of the G-BA (VerfO) for the active ingredient semaglutide. This benefit assessment was initiated due to new scientific findings from the completed PIONEER 6 study.

On 15 April 2021, the G-BA decided on the benefit assessment due to the presence of new scientific findings on the active ingredient semaglutide for the treatment of adults with insufficiently controlled type 2 diabetes mellitus in accordance with Section 35a paragraph 1 SGB V in conjunction with Section 3, paragraph 1, no. 4 AM-NutzenV and Chapter 5 Section 13 VerfO (BAnz AT 02.06.2021 B5). Section I. 1 of this resolution deletes the information on semaglutide in the version of the resolution of 2 May 2019 (BAnz AT 04.06.2019 B3) in the version of the resolution of 4 July 2019 (BAnz AT 12.09.2019 B3) and Section I. 2 supplements Annex XII to the Pharmaceuticals Directive with the amended information based on the benefit assessment due to the presence of new scientific findings. By resolution of 5 August 2021 (BAnz AT 22.10.2021 B3), the information on the active ingredient semaglutide under number 1 "Additional benefit of the medicinal product in relation to the appropriate comparator therapy" and under number 3 "Requirements for a quality-assured application" of Annex XII was amended.

In their ruling of 13 December 2024 (Berlin-Brandenburg Regional Social Court, file ref. L 1 KR 267/22 KL), the Berlin-Brandenburg Regional Social Court determined that the amendment - made by the G-BA's resolution of 15 April 2021 (BAnz AT 02.06.2021 B5) - to Annex XII of the Pharmaceuticals Directive for the benefit assessment of the active ingredient semaglutide in the version of the resolution of 5 August 2021 (BAnz AT 22.10.2021 B3) is invalid.

Consequently, the information added to Annex XII by Section I. 2 of the resolution of 15 April 2021 (BAnz AT 02.06.2021 B5) in the version of the resolution of 5 August 2021 (BAnz AT 22.10.2021 B3) on the active ingredient semaglutide for the treatment of adults with insufficiently controlled type 2 diabetes mellitus should be deleted. At the same time, the repeal - ordered by Section I. 1. resolution of 15 April 2021 (BAnz AT 02.06.2021 B5) - of the information added to Annex XII by resolution of 2 May 2019 (BAnz AT 04.06.2019 B3) in the version of the resolution of 4 July 2019 (BAnz AT 12.09.2019 B3) on the active ingredient semaglutide should be cancelled.

As a consequence, the information on the active ingredient semaglutide in the therapeutic indication for the treatment of adults with insufficiently controlled type 2 diabetes mellitus in Annex XII of the Pharmaceuticals Directive, which entered into force by resolution of 2 May 2019 (BAnz AT 04.06.2019 B3) in the version of the resolution of 4 July 2019 (BAnz AT 12.09.2019 B3) with effect from 2 May 2019 and 4 July 2019, continues to apply unchanged.

By resolution of 5 October 2023 (BAnz AT 22.01.2024 B2), Annex XIIa was supplemented with information on the active ingredient semaglutide of the assessed medicinal product in accordance with the resolution of 15 April 2021 pursuant to Section 35a paragraph 3 SGB V. This information in Annex XIIa was last amended by publication of the resolution of 8 October 2024 (BAnz 22.11.2024 B1). As a consequence of the findings in the ruling of the Berlin-Brandenburg Regional Social Court of 13 December 2024, the information on the active ingredient semaglutide, which is added to Annex XIIa at the level of the assessed medicinal product and goes beyond the information provided in the resolution of 2 May 2019 (BAnz AT 04.06.2019 B3) in the version of the resolution of 4 July 2019 (BAnz AT 12.09.2019 B3), should be deleted.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

At their session on 11 March 2025, the Subcommittee on Medicinal Products discussed the amendment of the information on the active ingredient semaglutide in Annexes XII and XIIa to the Pharmaceuticals Directive, and approved the draft resolution.

At their session on 20 March 2025, the plenary discussed and adopted the amendment to the information on the active ingredient semaglutide in Annexes XII and XIIa to the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
Working group Section 35a	5 March 2025	Consultation of the draft resolution
Subcommittee on Medicinal Products	11 March 2025	Consultation on the draft resolution to amend the information in Annexes XII and XIIa to the Pharmaceuticals Directive.
Plenum	20 March 2025	Adoption of the resolution on the amendment of the information in Annexes XII and XIIa to the Pharmaceuticals Directive.

Berlin, 20 March 2025

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

Prof. Hecken