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
Dapagliflozin (new therapeutic indication: type 1 diabetes mellitus) (repeal of the resolutions of 17 October 2019 and 26 November 2019)

of 18 March 2022

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 reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

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.

2. Key points of the resolution

The active ingredient dapagliflozin (Forxiga®) was approved for the first time on 11 November 2012 for the treatment of adult patients with type 2 diabetes mellitus. On 20 March 2019, dapagliflozin (Forxiga®) was approved for the therapeutic indication "insufficiently controlled type 1 diabetes mellitus as an adjunct to insulin in patients with BMI ≥ 27 kg/m^2, when insulin alone does not provide adequate glycaemic control despite optimal insulin therapy".

The Federal Joint Committee (G-BA) conducted a benefit assessment according to Section 35a of the German Social Code, Book V (SGB V) on dapagliflozin in the new therapeutic indication and added the active ingredient dapagliflozin to the Pharmaceuticals Directive in Annex XII by the resolution of 17 October 2019. With the resolution of 26 November 2019, the treatment costs were also adjusted.

On 25 October 2021, the marketing authorisation for dapagliflozin 5 mg for the therapeutic indication "type 1 diabetes mellitus as an adjunct to insulin in patients with a BMI ≥ 27 kg/m^2 when insulin alone does not provide adequate glycaemic control despite optimal insulin

therapy" was repealed by the European Commission at the request of the marketing authorisation holder. This was prompted by the diabetic ketoacidoses reported as a "frequent" side effect (at least 1 in 100 patients) in studies on type 1 diabetes mellitus with dapagliflozin. Other indications of dapagliflozin 5 mg and 10 mg are not affected by this change in the marketing authorisation. With this repeal of the marketing authorisation, the basis for the benefit assessment according to Section 35a (1) SGB V by the G-BA no longer applies. Consequently, the findings on the benefit assessment according to Section 35a (1) SGB V of dapagliflozin (new therapeutic indication: type 1 diabetes mellitus) in Annex XII of the AM-RL as amended by the resolutions of 17 October 2019 (BAnz AT 20.11.2019 B2) and of 26 November 2019 (BAnz AT 19.12.2019 B3) are to be repealed.

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

Session	Date	Subject of consultation
Working group Section 35a	1 March 2022	Consultation on the draft resolution
Subcommittee Medicinal product	9 March 2022	Consultation and consensus on the draft resolution on the repeal of the resolution
Plenum	18 March 2022	Adoption of the repeal of the resolution

Berlin, 18 March 2022

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

Prof. Hecken