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)
Belantamab mafodotin (repeal of the resolution of 5 October 2023)

of 4 April 2024

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.

For medicinal products for the treatment of rare diseases (orphan drugs) that are approved according to Regulation (EC) No. 141/2000 of the European Parliament and the Council of 16 December 1999, the additional medical benefit is considered to be proven through the grant of the marketing authorisation according to Section 35a, paragraph 1, sentence 11, 1st half of the sentence German Social Code, Book Five (SGB V). Evidence of the medical benefit and the additional medical benefit in relation to the appropriate comparator therapy do not have to be submitted (Section 35a, paragraph 1, sentence 11, 2nd half of the sentence SGB V). Section 35a, paragraph 1, sentence 11, 1st half of the sentence SGB V thus guarantees an additional benefit for an approved orphan drug, although an assessment of the orphan drug in accordance with the principles laid down in Section 35a, paragraph 1, sentence 3, No. 2 and 3 SGB V in conjunction with Chapter 5 Sections 5 et seq. of the Rules of Procedure (VerfO) of the G-BA has not been carried out. In accordance with Section 5, paragraph 8 AM-NutzenV, only the extent of the additional benefit is to be quantified indicating the significance of the evidence.

However, the restrictions on the benefit assessment of orphan drugs resulting from the statutory obligation to the marketing authorisation do not apply if the turnover of the medicinal product with the SHI at pharmacy sales prices and outside the scope of SHI-accredited medical care, including VAT exceeds € 30 million in the last 12 calendar months. According to Section 35a, paragraph 1, sentence 12 SGB V, the pharmaceutical company must then, within three months of being requested to do so by the G-BA, submit evidence according to Chapter 5, Section 5, paragraphs 1–6 VerfO, in particular regarding the additional medical benefit in relation to the appropriate comparator therapy as defined by the G-BA according to Chapter 5 Section 6 VerfO and prove the additional benefit in comparison with the appropriate comparator therapy.

In accordance with Section 35a, paragraph 2 SGB V, the G-BA decides whether to carry out the benefit assessment itself or to commission the Institute for Quality and Efficiency in Health Care (IQWiG). Based on the legal requirement in Section 35a, paragraph 1, sentence 11 SGB V that the additional benefit of an orphan drug is considered to be proven through the grant of the marketing authorisation the G-BA modified the procedure for the benefit assessment of orphan drugs at its session on 15 March 2012 to the effect that, for orphan drugs, the G-BA initially no longer independently determines an appropriate comparator therapy as the basis for the solely legally permissible assessment of the extent of an additional benefit to be assumed by law. Rather, the extent of the additional benefit is assessed exclusively on the basis of the approval studies by the G-BA indicating the significance of the evidence.

Accordingly, at its session on 15 March 2012, the G-BA amended the mandate issued to the IQWiG by the resolution of 1 August 2011 for the benefit assessment of medicinal products with new active ingredients in accordance with Section 35a, paragraph 2 SGB V to that effect that, in the case of orphan drugs, the IQWiG is only commissioned to carry out a benefit assessment in the case of a previously defined comparator therapy when the sales volume of the medicinal product concerned has exceeded the turnover threshold according to Section 35a, paragraph 1, sentence 12 SGB V and is therefore subject to an unrestricted benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment by the G-BA 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 belantamab mafodotin was first approved as a medicinal product on 25 August 2020 (Blenrep). The marketing authorisation was granted for the therapeutic indication: "Blenrep is indicated as monotherapy for the treatment of multiple myeloma in adult patients, who have received at least four prior therapies and whose disease is refractory to at least one proteasome inhibitor, one immunomodulatory agent, and an anti-CD38 monoclonal antibody, and who have demonstrated disease progression on the last therapy." This marketing authorisation is a conditional marketing authorisation for a medicinal product for the treatment of an orphan disease.

After the active ingredient belantamab mafodotin was placed on the market for the first time on 15 September 2020, the G-BA conducted a benefit assessment according to Section 35a and supplemented Annex XII of the Pharmaceuticals Directive with the active ingredient belantamab mafodotin by resolution of 4 March 2021.

The benefit assessment was based on the results of the single-arm phase II DREAMM-2 study. Against the background that the medicinal product Blenrep was granted conditional marketing authorisation, the European Medicines Agency EMA required that the results of the phase III DREAMM-3 study be submitted with regard to the evidence to be provided by the pharmaceutical company. The submission of the primary analyses of the results of this study to the EMA was expected by July 2024.

The G-BA had limited the period of validity of its resolution on the benefit assessment of belantamab mafodotin to 1 April 2023, including two amendment resolutions on the period of validity of the limitation, and made it subject to the condition that the expected interim results from the DREAMM-3 study must be submitted for the new benefit assessment after the expiry of the deadline.

In the ongoing benefit assessment procedure following expiry of the deadline set by the G-BA, the EMA recommended in September 2023 that the conditional marketing authorisation of belantamab mafodotin should not be extended because the efficacy of belantamab mafodotin could not be confirmed by the DREAMM-3 study required as part of the conditional marketing authorisation.

The G-BA completed the benefit assessment after expiry of the deadline by resolution of 5 October 2023 and, taking into account the corresponding EMA recommendations from September 2023, determined that a non-quantifiable additional benefit of belantamab mafodotin can be identified solely from a legal perspective in accordance with Section 35a, paragraph 1, sentence 11 half-sentence 1 SGB V.

The pharmaceutical company applied for a review of the EMA's scientific assessment of September 2023, which resulted in a new EMA recommendation in December 2023 not to renew the existing conditional marketing authorisation for belantamab mafodotin.

On 23 February 2024, the marketing authorisation for Blenrep was repealed by the European Commission due to the facts described above. With this repeal of the marketing authorisation, the basis for the benefit assessment according to Section 35a paragraph 1 SGB V by the G-BA no longer applies. Consequently, the resolution on belantamab mafodotin dated 5 October 2023 (BAnz AT 21.12.2023 B5) must 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	20 March 2024	Consultation on the draft resolution
Subcommittee Medicinal products	26 March 2024	Consultation and consensus on the draft resolution on the repeal of the resolution
Plenum	4 April 2024	Adoption of the repeal of the resolution

Berlin, 4 April 2024

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

Prof. Hecken