Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a (SGB V) Brexucabtagene autoleucel (relapsed or refractory mantle cell lymphoma); requirement of routine practice data collection and evaluations - amendment

of 18 June 2025

Contents

1. Legal basis

According to Section 35a, paragraph 3b, sentence 1 SGB V, the Federal Joint Committee (G-BA) can demand the pharmaceutical company to submit routine practice data collections and evaluations for the purpose of the benefit assessment within a reasonable period of time for the following medicinal products:

1. in the case of medicinal products authorised to be placed on the market in accordance with the procedure laid down in Article 14, paragraph 8 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (OJ L 136, 30.4.2004, p. 1), as last amended by Regulation 162 Rules of Procedure last revised: 16 December 2020 (EU) 2019/5 (OJ L 4, 7.1.2019, p. 24), or for which a marketing authorisation has been granted in accordance with Article 14-a of Regulation (EC) No. 726/2004; and
2. for medicinal products approved for the treatment of rare diseases under Regulation No. 141/2000.

2. Key points of the resolution

At their session on 21 July 2022, the G-BA decided on the requirement of routine practice data collection and evaluations for the active ingredient brexucabtagene autoleucel in accordance with Section 35a SGB V.

In accordance with the specifications of the resolution of 21 July 2022 in the form of the amendment resolutions of 16 March 2023 and 16 November 2023, a first interim analysis must be carried out 18 months after the start of the routine practice data collection in accordance with the specifications in the study protocol and statistical analysis plan and submitted to the G-BA. In the process, a check for discontinuation due to futility must also be carried out for each interim analysis. At the 1st interim analysis 18 months after the start of the data collection accompanying the application, a final sample size estimate is also to be made on the basis of the more precise effect assumptions that can then be made.

The pharmaceutical company submitted the first interim analysis to the G-BA in due time on 21 February 2025. With regard to the final sample size estimate, the pharmaceutical company states that no recalculation can be made on the basis of the 1st interim analysis, as the patient number is too small and effect assumptions are not possible.

The reasons given by the pharmaceutical company with regard to the missing final sample size estimate are understandable.

The final sample size estimate should therefore be submitted at the 2nd interim analysis 36 months after the start of the routine practice data collection.

3. Submission according to Section 35a, paragraph 3b, sentences 7 and 8 SGB V

A new submission procedure need not be carried out.

The adjustment of the time of submission of the final sample size estimate does not represent any significant change compared to the resolution on the requirement of routine practice data collection and evaluations of 21 July 2022, cf. Chapter 1 Section 14, paragraph 1 Rules of Procedure of the G-BA.

4. 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.

5. Process sequence

Subsequent to the adoption of the resolution of 21 July 2022, the pharmaceutical company informed the G-BA - with the submission of the first interim analysis 18 months after the start of the routine practice data collection - of the reasons for which a final sample size estimate was not feasible at the time of the first interim analysis. This results in changes to the requirements of the G-BA with regard to the routine practice data collection and evaluations.

The issue was discussed in the working group WG RPDC and in the Subcommittee on Medicinal Products.

At their session on 18 June 2025, the plenum adopted by consensus a resolution to amend the AM-RL.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	19 May 2025 5 June 2025	Consultation on the issue
Subcommittee on Medicinal Products	11 June 2025	Consultation on the amendment to the resolution of 18 June 2025
Plenum	18 June 2025	Resolution on the amendment to the resolution of 18 June 2025

Berlin, 18 June 2025

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

Prof. Hecken