Gemeinsamer Bundesausschuss

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

At their session on 18 June 2025, 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. In Annex XII, the information on the requirement of routine practice data collection and evaluations according to Section 35a, paragraph 3b, sentence 1 SGB V on the active ingredient brexucabtagene autoleucel in the version of the resolution of 21 July 2022 (Federal Gazette, BAnz AT 17.08.2022 B1), last amended by resolution of 16 November 2023 (Federal Gazette, BAnz AT 12.12.2023 B3), is amended as follows:

1. Section 1.4 "Evaluations of the data for the purpose of the benefit assessment" is amended as follows:

   The information "1st interim analysis" is replaced by the information "2nd interim analysis".

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 18 June 2025.

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

Berlin, 18 June 2025

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

Prof. Hecken