Gemeinsamer Bundesausschuss

# Resolution

## of the Federal Joint Committee on a Finding in the Procedure of Routine Practice Data Collection and Evaluations according to Section 35a, paragraph 3b SGB V: Brexucabtagene autoleucel (relapsed or refractory mantle cell lymphoma) – Review of study protocol and statistical analysis plan

of 18 June 2025

At their session on 18 June 2025, the Federal Joint Committee (G-BA) decided the following in the procedure of routine practice data collection and evaluations according to Section 35a paragraph 3b SGB V for the active ingredient brexucabtagene autoleucel (relapsed or refractory mantle cell lymphoma):

I. It is established that the pharmaceutical company has appropriately implemented the required amendments to the study documents specified in the declaratory resolution of 16 November 2023 and in the amendment resolution of 16 November 2023. The submitted, revised versions of the study protocol (version 4.0 of 17 February 2025) and the statistical analysis plan (SAP; version 4.0 of 17 February 2025) require further adaptation. The routine practice data collection can therefore only be continued under the condition that the following adaptations to the study protocol (version 4.0 of 17 February 2025) and to the SAP (version 4.0 of 17 February 2025), which are deemed mandatory for the implementation of the requirements pursuant to Section 58, paragraph 1, no. 1 VerfO, are made:

a) Data evaluation: Definition of the baseline value

In the 4th version of the study documents, the baseline value was defined as the last non-missing value before or up to the index date (if available). If this is not available, the last non-missing value up to the date of infusion of brexucabtagene autoleucel or the first administration of the comparator therapy is used. This definition is only partially appropriate. If the baseline value (the last non-missing value before or up to the index date) is not available, the first non-missing value after the index date must be assumed as the baseline value. It must be ensured that the baseline collection is prior to any treatment.

In order to be able to take into account a possible time lag between baseline collection and the index date when interpreting the results, the distribution of the time deviations of the respective baseline collection from the index date should be presented transparently for each treatment group.

This procedure must be recorded in the study documents.

b) Data evaluation: Non-severe specific adverse events (AEs)

In the 4th version of the study documents, the collection of any specific AEs with an indication of the respective severity grade was deleted. This deletion is inappropriate. Specific AEs must be evaluated regardless of their severity grade and specific AEs that lead to a significant impairment of the activity of daily living or with CTCAE grade ≥ 3 must also be evaluated.

The deletion must be reversed in the study documents.

c) Data evaluation: Patient-reported outcomes, death as a clinically relevant deterioration

In the 4th version of the SAP, an addition was made to the definition of the time to clinically relevant deterioration (confirmed once). The event of death is rated as a clinically relevant deterioration. This addition is inappropriate in the context of the evaluation of patient-reported outcomes relating to symptomatology and health-related quality of life. Evaluations in which deaths are not rated as an event must be presented. In the context of the evaluation of patient-reported outcomes with regard to symptomatology and health-related quality of life, deaths can at best be rated as confirmation of a previously measured deterioration.

The addition must be reversed in the study documents.

d) Data evaluation: Patient-reported outcomes, evaluation

In the 4th version of the SAP, it was added that a questionnaire is considered completed if at least one item has been filled out. This addition is inappropriate. The number of patients for whom analysable data is available must be shown for each scale. The questionnaires must be evaluated in accordance with the manuals.

The addition must be reversed in the study documents.

In order to avoid inconsistencies, the pharmaceutical company must check whether the need for changes in the study protocol described here leads to corresponding subsequent changes in the SAP and vice versa.

II. As part of the new benefit assessment, the G-BA reserves the right to conclusively assess effects on the RPDC study that arise due to changes to the study protocol submitted for the first time or the statistical analysis plan submitted for the first time by the pharmaceutical company and that do not comply with the requirements of the G-BA in accordance with the declaratory resolutions in the procedure of routine practice data collection for the active ingredient brexucabtagene autoleucel in the therapeutic indication of relapsed or refractory mantle cell lymphoma.

III. The revised study protocol and the revised SAP are to be submitted to the G-BA by 21 August 2026.

IV. 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