Gemeinsamer Bundesausschuss

Justification

on the Resolution of the Federal Joint Committee (G-BA) on the Finding in the Procedure of Routine Practice Data Collection and Evaluations according to Section 35a paragraph 3b SGB V:
Loncastuximab tesirine (relapsed or refractory diffuse large B-cell lymphoma) – Submission of study protocol and statistical analysis plan

of 22 January 2026

Contents

Courtesy translation – only the German version is legally binding.

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.

According to Section 35a, paragraph 3b, sentence 10 SGB V in conjunction with Chapter 5 Section 60 Rules of Procedure of the G-BA (VerfO), the G-BA reviews the data obtained and the obligation to collect data at regular intervals, at least every eighteen months.

2. Key points of the resolution

At its session on 17 July 2025, the G-BA decided on the requirement of routine data collection and evaluations for the active ingredient loncastuximab tesirine in accordance with Section 35a, paragraph 3b, sentence 1 SGB V.

By this resolution, the pharmaceutical company was instructed to prepare a study protocol and a statistical analysis plan (SAP) before carrying out the routine practice data collection and evaluations and to submit it to the G-BA by 17 December 2025 at the latest. The pharmaceutical company did not submit drafts of a study protocol and a statistical analysis plan to the G-BA.

This result shall be communicated to the National Association of Health Insurance Funds for the purpose of a decision pursuant to Section 130b, paragraph 3, sentence 9 SGB V.

3. Process sequence

According to the resolution of 17 July 2025 on the requirement of routine practice data collection and evaluations for the active ingredient loncastuximab tesirine, the pharmaceutical company should have submitted the final drafts of a study protocol and a statistical analysis plan to the G-BA for approval by 17 December 2025.

The pharmaceutical company did not submit drafts of a study protocol and a statistical analysis plan to the G-BA.

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

At their session on 22 January 2026, the plenum decided that the routine practice data collection will not be carried out.

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Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	8 January 2026	Advice on the review of the pharmaceutical company's obligation to submit the study protocol and SAP
Subcommittee on Medicinal Products	13 January 2026	Consultation on the outcome of the review of the pharmaceutical company's obligation to submit the study protocol and SAP
Plenum	22 January 2026	Resolution on the review of the pharmaceutical company’s obligation to submit the study protocol and SAP

Berlin, 22 January 2026

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

Prof. Hecken

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