Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) on the Non-amendment of the Pharmaceuticals Directive (AM-RL):
Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V
Glofitamab (relapsed or refractory diffuse large B-cell lymphoma);
restriction of the authority to supply care

of 18 June 2025

Contents

1. Legal basis

According to Section 35a, paragraph 3b, sentence 2 SGB V, the Federal Joint Committee (G-BA) may decide for a medicinal product that is the subject of a resolution according Section 35a, paragraph 3b, sentence 1 SGB V that the authority to supply insured persons such a medicinal product at the expense of the statutory health insurance is restricted to those care providers who participate in the required routine practice data collection according to Section 35a, paragraph 3b SGB V (restriction of the care providers' authority to supply care). The resolution is to be published online and is part of the Pharmaceuticals Directive (AM-RL).

2. Key points of the resolution

At their session on 5 June 2025, the G-BA decided to discontinue the consultation procedure on the requirement of routine practice data collection and evaluations for the active ingredient glofitamab in the treatment of adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy, who are ineligible for CAR T-cell therapy and stem cell transplant.

Since the active ingredient glofitamab is thus not the subject of a resolution according to Section 35a, paragraph 3b, sentence 1 SGB V for the above-mentioned patient group of the currently approved therapeutic indication, the G-BA decides by the present resolution not to amend Annex XII of the Pharmaceuticals Directive with regard to a restriction of the authority to supply care for the active ingredient glofitamab in the treatment of:

"Adults with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), after two or more lines of systemic therapy, who are ineligible for CAR T-cell therapy and stem cell transplant".

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

In order to hold consultations and prepare a recommendation for a resolution on the initiation of a written statement procedure for the restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V, the Subcommittee on Medicinal Products commissioned a working group (WG routine practice data collection (RPDC)) consisting of the members nominated by the leading organisations of the care providers, the members nominated by the SHI umbrella organisation, and the representative(s) of the patient organisations. Representatives of the IQWiG also participate in the sessions. The working group discussed the amendment of the AM-RL at their session on 2 May 2025.

The draft resolution to initiate a written statement procedure was discussed at the session of the Subcommittee on Medicinal Products on 6 May 2025 and the draft resolution was consented to.

At their session on 6 May 2025, the Subcommittee unanimously decided to initiate the written statement procedure according to Chapter 1 Section 10, paragraph 1 of the G-BA's Rules of Procedure.

Statements were received during the written statement procedure.

The evaluation of the written statements received was discussed at the session of the subcommittee on 11 June 2025, and the proposed resolution was approved.

At their session on 18 June 2025, the plenum adopted a resolution not to amend the Pharmaceuticals Directive.

Chronological course of consultation

Session	Date	Subject of consultation
WG RPDC	2 May 2025	Consultation on the amendment of the AM-RL
Subcommittee on Medicinal Products	6 May 2025	Discussion and consensus on the draft resolution Resolution to initiate the written statement procedure on the amendment of the AM-RL Scheduling the oral hearing
Subcommittee on Medicinal Products	11 June 2025	Concluding discussion of the draft resolution
Plenum	18 June 2025	Adoption of the resolution on the non-amendment of Annex XII AM-RL

Berlin, 18 June 2025

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

Prof. Hecken