Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee (G-BA) on a 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

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 DD. Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), with regard to a restriction of the authority to supply care, as 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, was discontinued by G-BA's resolution of 5 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