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 Exagamglogene autotemcel (β-thalassaemia); restriction of the authority to supply care

of 1 February 2024

At its session on 1 February 2024, 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 (BAnz AT DD.MM.YYYY BX), with regard to a restriction of the authority to supply care, as the consultation procedure for the requirement of routine practice data collection and evaluations for the active ingredient exagamglogene autotemcel in the treatment of β-thalassaemia was suspended by resolution of the G-BA of 1 February 2024.

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

Berlin, 1 February 2024

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

Prof. Hecken