Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee on an Amendment of the Pharmaceuticals Directive: Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V: Exagamglogene autotemcel (sickle cell disease); requirement of routine practice data collection and evaluations - Amendment

of 7 November 2024

At its session on 7 November 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 D Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the information on the requirement of routine practice data collection and evaluations according to Section 35a, paragraph 3b, sentence 1 SGB V on the active ingredient Exagamglogene autotemcel in the version of the resolution of 21 December 2023 is amended as follows:

Section 1.1 "Research question according to PICO scheme" is amended as follows:

In the table, the word "Voxelotor" is deleted from the "Comparator" row.

III. The resolution shall enter into force on the date on which Exagamglogene autotemcel is first placed on the market.

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

Berlin, 7 November 2024

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

Prof. Hecken