Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee (G-BA) on an 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 (sickle cell disease); requirement of routine practice data collection and evaluations - amendment

of 18 September 2025

At their session on 4 September 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 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 (Federal Gazette, BAnz AT 18.02.2025 B4), last amended by resolution of DD Month YYYY (Federal Gazette, BAnz AT 12.02.2025 B1), is amended as follows:

1. After the information "Therapeutic indication for the requirement of routine practice data collection and evaluations (resolution of 21 December 2023):", the information "see therapeutic indication according to the ongoing marketing authorisation procedure" is replaced by the information "Casgevy is indicated for the treatment of severe sickle cell disease (SCD) in patients 12 years of age and older with recurrent vaso-occlusive crises (VOCs) for whom haematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen (HLA)-matched related HSC donor is not available".
2. In number 1.1 "Research question according to PICO scheme", the information "who have the genotype ßS/ßS, ßS/ß0 or ßS/ß+, who are eligible for haematopoietic stem cell transplantation and for whom a human leukocyte antigen (HLA)-matched related HSC donor is not available" in the "Population" line is replaced by the information "for whom haematopoietic stem cell (HSC) transplantation is appropriate and a human leukocyte antigen (HLA)-matched related HSC donor is not available".

III. The resolution will enter into force on the day of its publication on the website of the G-BA on 18 September 2025.

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

Berlin, 18 September 2025

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

Prof. Hecken