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);
restriction of the authority to supply care

of 21 December 2023

At its session on 21 December 2023, 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 following information shall be added after number 3 to the information on the requirement of routine practice data collection and evaluations of Exagamglogene autotemcel in accordance with the resolution of 21 December 2023:

Exagamglogene autotemcel

Resolution of: 21 December 2023
Entry into force on: 15 January 2025
Federal Gazette, BAnz AT DD. MM YYYY Bx

Restriction of the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V

For the active ingredient exagamglogene autotemcel in the treatment of:

"Patients 12 years of age and older with severe sickle cell disease with recurrent vaso-occlusive crises who have the genotype βS/βS, βS/β0 or βS/β+, for whom haematopoietic stem cell transplantation is an option and no human leukocyte antigen (HLA)-compatible, related haematopoietic stem cell donor is available"

the authority to supply care according to Section 35a, paragraph 3b, sentence 2 SGB V is limited to those care providers who participate in the required routine practice data collection.

Care providers within the meaning of this resolution are physicians participating in SHI-accredited medical care, medical care centres and facilities according to Section 95 SGB V as well as hospitals approved for care provision according to Section 108 SGB V.

Participation in the required routine practice data collection is ensured by the proper (proven in writing) participation of the (approved) healthcare provider in the data collection for the required routine practice data collection on the basis of the confirmed study protocol of the pharmaceutical company.

II. Entry into force

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

The restriction of the authority to supply care to those care providers who participate in the required routine practice data collection, as regulated in the resolution, only takes effect with the start of the routine practice data collection, which is determined in a separate resolution.

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

Berlin, 21 December 2023

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

Prof. Hecken