Resolution

Gemeinsamer Bundesausschuss

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 Betibeglogene Autotemcel (β-Thalassaemia) (Treatment Costs)

of 3 December 2020

At its session on 3 December 2020, the Federal Joint Committee (G-BA) resolved to amend the Directive on the Prescription of Medicinal Products in SHI-accredited Medical Care (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 on DD MM YYYY (Federal Gazette, BAnz AT DD MM YYYY Bx) as follows:

I. In Annex XII, the information on the benefit assessment of the active ingredient betibeglogene autotemcel in the version of the resolution of 14 May 2020 (Federal Gazette, BAnz AT 23 June 2020 B5) in section "4. Treatment costs" is amended as follows:

Under section "4. Treatment costs", the information is adopted as follows:

"Annual treatment costs:

Designation of the therapy	Annual treatment costs/patient
Betibeglogene autotemcel[2]	€ 1,874,250
Additionally required SHI services	not quantifiable

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 April 2020".

II. The resolution will enter into force with effect from the day of its publication on the internet on the website of the G-BA on 3 December 2020.

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

[2] Because HSC mobilisation and stem cell apheresis are part of the production of the medicinal product in accordance with Section 4, paragraph 14 AMG, no further costs are incurred in this respect for the medicinal product to be assessed.

Berlin, 3 December 2020

Federal Joint Committee
in accordance with Section 91 SGB V
The Chair

Prof. Hecken