Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee (G-BA) on a non-amendment of the Pharmaceuticals Directive Annex XII - Procedure for initiating a new benefit assessment according to Section 35a paragraph 1 SGB V in conjunction with Section 3 paragraph 1 No. 4 Ordinance on the Benefit Assessment of Pharmaceuticals (AM-NutzenV) and Chapter 5 Section 13 Rules of Procedure (VerfO) – Benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V: Dolutegravir

of 15 September 2022

At its session on 15 September 2022, the Federal Joint Committee (G-BA) resolved to amend Annex XII of the Pharmaceuticals Directive (AM-RL) in the version dated 18 December 2008 / 22 January 2009 (Federal Gazette, BAnz. No. 49a of 31 March 2009), which was last amended by the announcement of the resolution of 21 June 2022 (Federal Gazette, BAnz AT 09.09.2022 B1) due to the initiation of a new benefit assessment according to Section 35a paragraph 1 SGB V in conjunction with Section 3 paragraph 1 No. 4 AM-NutzenV and Chapter 5 Section 13 VerfO: Annex XII – Benefit assessment of medicinal products with new active ingredients according to Section 35a SGB V on the active ingredient dolutegravir not to be amended by the resolution of 20 August 2020, last amended on 2 December 2021 (Federal Gazette, BAnz AT 17.12.2021 B8).

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

Berlin, 15 September 2022

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

Prof. Hecken