

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 Ataluren (repeal of the resolution of 1 December 2016)

of 20 November 2025

At their session on 20 November 2025, the Federal Joint Committee (G-BA) resolved not 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. The findings on the benefit assessment of the active ingredient ataluren in Annex XII of the Pharmaceuticals Directive in the version of the resolution of 1 December 2016 (BAnz AT 22.12.2016 B4) are deleted.
- II. The resolution will enter into force on the day of its publication on the website of the G-BA on 20 November 2025.

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

Berlin, 20 November 2025

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

Prof. Hecken