Gemeinsamer Bundesausschuss

Resolution

of the Federal Joint Committee (G-BA) on a Non-amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V Iptacopan (paroxysmal nocturnal haemoglobinuria); restriction of the authority to supply care

of 20 March 2025

At its session on 20 March 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 DD. Month YYYY (BAnz AT DD.MM.YYYY BX), with regard to a restriction of the authority to supply care, as the consultation procedure for the requirement of routine data collection and evaluations for the active ingredient iptacopan in the treatment of therapy-naïve adults with paroxysmal nocturnal haemoglobinuria who have haemolytic anaemia was suspended by resolution of the G-BA of 20 March 2025.

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

Berlin, 20 March 2025

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

Prof. Hecken