Gemeinsamer Bundesausschuss

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
Rucaparib (after at least 2 prior therapies, with BRCA mutations) (Repeal of the Resolution of 15 August 2019)

of 1 December 2022

At its session on 1 December 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), 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of the active ingredient Rucaparib in the version of the resolution of 15 August 2019 (BAnz AT 08.10.2019 B5) are repealed for the following therapeutic indication:

> Rubraca is indicated as "as monotherapy treatment of adult patients with platinum sensitive, relapsed or progressive, BRCA mutated (germline and/or somatic), high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer, who have been treated with two or more prior lines of platinum based chemotherapy, and who are unable to tolerate further platinum based chemotherapy".

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 1 December 2022.

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

Berlin, 1 December 2022

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

Prof. Hecken