

Draft resolution



Gemeinsamer
Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL):

Annex XII – Amendment of Information on the Period of Validity of a Resolution on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V

Niraparib (Ovarian Carcinoma, Tubal Carcinoma, or Primary Peritoneal Carcinoma)

of 20 August 2020

At its session on 20 August 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 Month YYYY (Federal Gazette, BAnz AT DD MM YYYY BX), as follows:

- I. In Annex XII, the provision under II. 2. concerning the period of validity of the resolution of 2 April 2020 on the benefit assessment of niraparib will be amended as follows:

The entry “1 October 2020”, which entered into force with the resolution of 2 April 2020, shall be replaced by “1 February 2021”.

- 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 20 August 2020.

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

Berlin, 20 August 2020

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

Prof. Hecken