Gemeinsamer Bundesausschuss

Justification

of the Resolution of the Federal Joint Committee (G-BA) 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

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1. Legal basis

According to Section 35a paragraph 1 German Social Code, Book Five (SGB V), the Federal Joint Committee (G-BA) assesses the benefit of reimbursable medicinal products with new active ingredients. This includes in particular the assessment of the additional benefit and its therapeutic significance. The benefit assessment is carried out on the basis of evidence provided by the pharmaceutical company, which must be submitted to the G-BA electronically, including all clinical trials the pharmaceutical company has conducted or commissioned, at the latest at the time of the first placing on the market as well as the marketing authorisation of new therapeutic indications of the medicinal product, and which must contain the following information in particular:

1. approved therapeutic indications,
2. medical benefit,
3. additional medical benefit in relation to the appropriate comparator therapy,
4. number of patients and patient groups for whom there is a therapeutically significant additional benefit,
5. treatment costs for the statutory health insurance funds,
6. requirements for a quality-assured application.

The G-BA may commission the Institute for Quality and Efficiency in Health Care (IQWiG) to carry out the benefit assessment. According to Section 35a, paragraph 2 SGB V, the assessment must be completed within three months of the relevant date for submission of the evidence and published on the internet.

According to Section 35a, paragraph 3 SGB V, the G-BA decides on the benefit assessment within three months of its publication. The resolution is to be published on the internet and forms part of the Pharmaceuticals Directive.

2. Key points of the resolution

The active ingredient rucaparib (Rubraca®) was first approved as a medicinal product on 23 May 2018. The marketing authorisation was granted for the therapeutic indication "Rubraca is indicated 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". On 23 January 2019, marketing authorisation was granted for the therapeutic indication "Rubraca is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive, relapsed, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy".

After the active ingredient rucaparib was placed on the market for the first time on 1 March 2019, the G-BA conducted benefit assessments according to Section 35a for both therapeutic

indications and supplemented the Pharmaceuticals Directive in Annex XII with the resolutions of 15 August 2019 by the active ingredient rucaparib.

On 21 September 2022, the marketing authorisation for rucaparib for the therapeutic indication "Rubraca is indicated 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" was repealed by the European Commission. This was prompted by the phase 3 ARIEL4 study, which investigated rucaparib versus chemotherapy in patients with relapsed, BRAC-mutated, high-grade epithelial ovarian, fallopian tube or peritoneal carcinoma. Results from the ARIEL4 study show shorter overall survival with rucaparib compared to chemotherapy.

With this repeal of the marketing authorisation for this therapeutic indication, the basis for the benefit assessment according to Section 35a, paragraph 1 SGB V by the G-BA no longer applies. Consequently, the findings on the benefit assessment of rucaparib according to Section 35a, paragraph 1 SGB V (after at least 2 prior therapies, with BRCA mutations) in Annex XII of the AM-RL in the version of the resolution of 15 August 2019 (BAnz AT 08.10.2019 B5) are to be repealed.

The indication "Rubraca is indicated as monotherapy for the maintenance treatment of adult patients with platinum-sensitive, relapsed, high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) to platinum-based chemotherapy" is not affected by the change in the marketing authorisation. Accordingly, the resolution also passed on 15 August 2019 (maintenance treatment) is not affected.

3. Bureaucratic costs calculation

The proposed resolution does not create any new or amended information obligations for care providers within the meaning of Annex II to Chapter 1 VerfO and, accordingly, no bureaucratic costs.

4. Process sequence

Session	Date	Subject of consultation
Working group Section 35a	1 November 2022	Consultation on the draft resolution
Subcommittee Medicinal products	22 November 2022	Consultation and consensus on the draft resolution on the repeal of the resolution
Plenum	1 December 2022	Adoption of the repeal of the resolution

Berlin, 1 December 2022

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

Prof. Hecken