

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 (reassessment after the deadline: ovarian cancer,
fallopian tube cancer or primary peritoneal cancer,
maintenance treatment)

of 21 September 2023

At its session on 21 September 2023, the Federal Joint Committee (G-BA) resolved 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. Annex XII is amended as follows:

- 1. The information on Rucaparib in the version of the resolution of 15 August 2019 (Federal Gazette, BAnz AT 8 October 2019 B4) is repealed.**
- 2. Annex XII shall be amended in alphabetical order to include the active ingredient Rucaparib as follows:**

Rucaparib

Resolution of: 21 September 2023
Entry into force on: 21 September 2023
Federal Gazette, BAnz AT DD. MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 24 May 2018):

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.

Therapeutic indication of the resolution (resolution of 21 September 2023):

See therapeutic indication according to marketing authorisation.

1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy

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

Appropriate comparator therapy:

Patient-individual therapy with selection of:

- olaparib,
- niraparib and
- monitoring wait-and-see approach (only for patients who have already received a PARP inhibitor);

taking into account prior therapy with a PARP inhibitor

Extent and probability of the additional benefit of rucaparib compared to the appropriate comparator therapy:

The additional benefit is deemed not to have been proven.

Study results according to endpoints:¹

No data available.

¹ Data from the dossier assessment of the G-BA unless otherwise indicated.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.
Explanations: ↑: statistically significant and relevant positive effect with low/unclear reliability of data ↓: statistically significant and relevant negative effect with low/unclear reliability of data ↑↑: statistically significant and relevant positive effect with high reliability of data ↓↓: statistically significant and relevant negative effect with high reliability of data ↔: no statistically significant or relevant difference ∅: No data available. n.a.: not assessable		

2. Number of patients or demarcation of patient groups eligible for treatment

approx. 1,750 to 2,270 patients

3. Requirements for a quality-assured application

The requirements in the product information are to be taken into account. The European Medicines Agency (EMA) provides the contents of the product information (summary of product characteristics, SmPC) for Rubraca (active ingredient: rucaparib) at the following publicly accessible link (last access: 3 May 2023):

https://www.ema.europa.eu/en/documents/product-information/rubraca-epar-product-information_en.pdf

Treatment with rucaparib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, specialists in gynaecology, and other specialists participating in the Oncology Agreement, all of whom are experienced in the treatment of patients with ovarian cancer.

4. Treatment costs

Annual treatment costs:

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Rucaparib	€ 56,995.24
Appropriate comparator therapy:	

Designation of the therapy	Annual treatment costs/ patient
Olaparib	€ 58,206.42
Niraparib	€ 70,075.96
Monitoring wait-and-see approach	incalculable

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 September 2023

Costs for additionally required SHI services: not applicable

5. Designation of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V that can be used in a combination therapy with the assessed medicinal product

In the context of the designation of medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V, the following findings are made:

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

- No designation of medicinal products with new active ingredients that can be used in combination therapy pursuant to Section 35a, paragraph 3, sentence 4 SGB V, as the active ingredient to be assessed is an active ingredient authorised in monotherapy.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 21 September 2023.

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

Berlin, 21 September 2023

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

Prof. Hecken