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 (new therapeutic indication: ovarian, fallopian tube, or primary peritoneal cancer, maintenance treatment after first-line therapy)

of 6 June 2024

At its session on 6 June 2024, 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. In Annex XII, the following information shall be added after No. 5 to the information on the benefit assessment of Rucaparib in accordance with the resolution of 21 September 2023:

Rucaparib

Resolution of: 6 June 2024
Entry into force on: 6 June 2024
Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 15 November 2023):

Rubraca is indicated as monotherapy for the maintenance treatment of adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in response (complete or partial) following completion of first-line platinum-based chemotherapy.

Therapeutic indication of the resolution (resolution of 6 June 2024):

See new therapeutic indication according to marketing authorisation.

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

Adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in remission (complete or partial) following completion of first-line platinum-based chemotherapy; maintenance treatment

Appropriate comparator therapy:

A patient-individual therapy under selection of:

- bevacizumab
- olaparib
- niraparib
- olaparib in combination with bevacizumab

under consideration of:

- prior therapy
- the presence of a BRCA 1/2 mutation
- the presence of genomic instability

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

An additional benefit is not proven.

Study results according to endpoints:[1]

Adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in remission (complete or partial) following completion of first-line platinum-based chemotherapy; maintenance treatment

There are no assessable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	n.a.	There are no assessable data.
Morbidity	n.a.	There are no assessable data.
Health-related quality of life	n.a.	There are no assessable data.
Side effects	n.a.	There are no assessable data.
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

Adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in remission (complete or partial) following completion of first-line platinum-based chemotherapy; maintenance treatment

Approx. 3,250 to 3,590 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: 7 May 2024):

1 Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A23-134) unless otherwise indicated.

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:

The annual treatment costs shown refer to the first year of treatment.

Adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in remission (complete or partial) following completion of first-line platinum-based chemotherapy; maintenance treatment

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Rucaparib	€ 59,511.30
Appropriate comparator therapy:	
A patient-individual therapy under selection of:	
Bevacizumab	€ 63,629.43
Olaparib	€ 60,805.74
Olaparib + bevacizumab	€ 124,435.17
Niraparib	€ 48,808.06

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 1 May 2024)

Costs for additionally required SHI services: not applicable

Other SHI benefits:

Designation of the therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Bevacizumab	Preparation of parenteral solutions with monoclonal antibodies	€ 100	1	15.7	€ 1,570.00

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:

Adult patients with advanced (FIGO Stages III and IV) high-grade epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in remission (complete or partial) following completion of first-line platinum-based chemotherapy; maintenance treatment

– 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.

The designation of combinations exclusively serves the implementation of the combination discount according to Section 130e SGB V between health insurance funds and pharmaceutical companies. The findings made neither restrict the scope of treatment required to fulfil the medical treatment mandate, nor do they make statements about expediency or economic feasibility.

II. The resolution will enter into force on the day of its publication on the website of the G-BA on 6 June 2024.

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

Berlin, 6 June 2024

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

Prof. Hecken