Resolution

Gemeinsamer Bundesausschuss

of the Federal Joint Committee (G-BA) on an Amendment of the Pharmaceuticals Directive (AM-RL): Annex XII – Resolutions on the Benefit Assessment of Medicinal Products with New Active Ingredients According to Section 35a SGB V Rucaparib (after at least 2 previous therapies, with BRCA mutations)

of 15 August 2019

At its session on 15 August 2019, 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. Annex XII shall be amended in alphabetical order to include the active ingredient rucaparib as follows:

Rucaparib

Resolution of: 15 August 2019
Entry into force on: 15 August 2019
Federal Gazette, BAnz AT DD MM YYYY Bx

Therapeutic indication (according to the marketing authorisation of 23 May 2018):

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.

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

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

Appropriate comparator therapy:

Monotherapy with topotecan *or* monotherapy with pegylated liposomal doxorubicin (PLD)

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:

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

There is no data that would allow for the assessment of the additional benefit.

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

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

≤ approx. 95 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: 5 July 2019):

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

Only specialists in internal medicine, haematology and oncology with experience treating patients with ovarian cancer, and specialist in gynaecology and other doctors from other specialisms participating in the oncology agreement may initiate and monitor treatment with rucaparib.

This medicinal product received a conditional marketing authorisation. This means that further evidence of the benefit of the medicinal product is expected. The EMA will evaluate new information on this medicinal product at least annually and update the product information if necessary.

4. Treatment costs

Annual treatment costs:

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

Designation of the therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Rucaparib	€ 106,668.82
Appropriate comparator therapy:	
Topotecan	€ 19,012.80
Pegylated liposomal doxorubicin (PLD)	€ 46,068.36

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 July 2019)

Costs for additionally required SHI services: not applicable

Other SHI services:

Designation of the therapy	Type of service	Costs/ Unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Topotecan	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	5	17	€ 6,885

Pegylated liposomal doxorubicin (PLD)	Surcharge for production of a parenteral preparation containing cytostatic agents	€ 81	1	13	€ 1,053

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 15 August 2019.

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

Berlin, 15 August 2019

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

Prof Hecken