Resolution

of the Federal Joint Committee on an amendment to the Pharmaceuticals Directive (AM-RL)
Annex XII –Benefit Assessment of Medicinal Products with New Active Ingredients according to Section 35a SGB V: Niraparib (New therapeutic indication: ovarian carcinoma, fallopian tube carcinoma or primary peritoneal carcinoma, FIGO stages III and IV, maintenance therapy)

of 20 May 2021

At its session on 20 May 2021, 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 on DD Month YYYY (Federal Gazette, BAnz AT DD.MM.YYYY BX), as follows:

I. In Annex XII, the following information shall be added after No. 4 to the information on the benefit assessment of Niraparib in accordance with the resolution of 2 April 2020, last amended on 20 August 2020:

Niraparib

Resolution of: 20 May 2021
Entry into force on: 20 May 2021
BAnz AT DD MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 27 October 2020):

Zejula is used as monotherapy for maintenance treatment in adult patients with advanced epithelial (FIGO stages III and IV) high-grade carcinoma of the ovaries, fallopian tubes or with primary peritoneal carcinoma who have a response (complete or partial) after first-line platinum-based chemotherapy.

Therapeutic indication of the resolution (resolution of 20/5/2021):

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 epithelial (stages III and IV), high-grade carcinoma of the ovaries, fallopian tubes, or with primary peritoneal carcinoma who are in remission (complete or partial) following completed first-line platinum-based chemotherapy; maintenance therapy

Appropriate comparator therapy:

A therapy according to the doctor's instructions taking into account
- Monitoring wait-and-see approach (after previous therapy with carboplatin in combination with paclitaxel)
- Bevacizumab (only after previous therapy with carboplatin in combination with paclitaxel and bevacizumab)

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

An additional benefit is not proven.

Study results according to endpoints:

Adult patients with advanced epithelial (stages III and IV), high-grade carcinoma of the ovaries, fallopian tubes, or with primary peritoneal carcinoma who are in remission (complete or partial) following completed first-line platinum-based chemotherapy; maintenance therapy

There are no suitable data.

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ Risk of bias	Summary
Mortality	n.a.	There are no evaluable data.
Morbidity	n.a.	There are no evaluable data.
Health-related quality of life	n.a.	There are no evaluable data.
Side effects	n.a.	There are no evaluable 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
∅: There is no usable data for the benefit assessment.
n.a.: not assessable

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

Adult patients with advanced epithelial (stages III and IV), high-grade carcinoma of the ovaries, fallopian tubes, or with primary peritoneal carcinoma who are in remission (complete or partial) following completed first-line platinum-based chemotherapy; maintenance therapy

approx. 2010 to 2810 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 Zejula (active ingredient: niraparib) at the following publicly accessible link (last access: 24 February 2021):

https://www.ema.europa.eu/en/documents/product-information/zejula-epar-product-information_de.pdf

Treatment with Niraparib should only be initiated and monitored by specialists in internal medicine, haematology and oncology, specialists in gynaecology and obstetrics and others, and specialists participating in the Oncology Agreement who are experienced in the treatment of patients with ovarian carcinoma.

4. Treatment costs

Annual treatment costs:

Name of therapy	Annual treatment costs/patient
Medicinal product to be assessed:	
Niraparib	€ 54,304.53
Appropriate comparator therapy:	
A therapy according to the doctor's instructions taking into account	
monitoring wait-and-see approach	incalculable
Bevacizumab	€ 69,042.48

Costs after deduction of statutory rebates (LAUER-TAXE®, as last revised: 1 May 2021).

Costs for additionally required SHI services: not applicable

Other SHI services:

Name of therapy	Type of service	Costs/ unit	Number/ cycle	Number/ patient/ year	Costs/ patient/ year
Bevacizumab	Surcharge for the preparation of a parenteral solution containing monoclonal antibodies	€ 71	1	15.7	€ 1,114.70

II. The resolution will enter into force on the day of its publication on the internet on the website of the G-BA on 20 May 2021.

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

Berlin, 20 May 2021

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

Prof. Hecken