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 Palbociclib (reassessment after the deadline: breast cancer, HR+, HER2-, combination with aromatase inhibitor)

of 15 December 2022

At its session on 15 December 2022, 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:**

**The information on Palbociclib in the version of the resolution of 18 May 2017 (BAnz AT 16.06.2017 B2) last revised on 15 October 2020 remains part of the Pharmaceuticals Directive with the repeal of the limitation for the patient group a1 in accordance with the following changes:**

**1. The information for Palbociclib on the date and entry into force of the resolutions is adopted as follows:**

"Resolution of: 18 May 2017
Entry into force on: 18 May 2017
BAnz AT 16.06.2017 B2

Resolution of: 20 September 2018
Entry into force on: 20 September 2018
BAnz AT 25.10.2018 B3

Resolution of: 22 March 2019
Entry into force on: 22 March 2019
BAnz AT 16.04.2019 B3

Resolution of: 18 July 2019
Entry into force on: 18 July 2019
BAnz AT 26.08.2019 B8

Resolution of: 15 October 2020
Entry into force on: 15 October 2020
BAnz AT 26.01.2021 B7

Resolution of: 15 December 2022
Entry into force on: 15 December 2022
Federal Gazette, BAnz AT DD MM YYYY Bx“

**Therapeutic indication (according to the marketing authorisation of 9 November 2016):**

IBRANCE is indicated for the treatment of hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:

- in combination with an aromatase inhibitor
- in combination with fulvestrant in women who have received prior endocrine therapy (see section 5.1 of the product information)

In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinizing hormone-releasing hormone (LHRH) agonist.

**Therapeutic indication of the resolution (resolution of 15 December 2022):**

Ibrance in combination with an aromatase inhibitor is indicated for the first-line treatment of postmenopausal patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.

**2. The findings under "1. Additional benefit of the medicinal product in relation to the appropriate comparator therapy" for the patient populations "a1)" is adopted as follows:**

"

a1) First-line treatment of postmenopausal patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer

**Appropriate comparator therapy:**

- Anastrozole

or

- Letrozole

or

- Fulvestrant

or

- Tamoxifen, if necessary, if aromatase inhibitors are unsuitable

or

- Ribociclib in combination with a non-steroidal aromatase inhibitor (anastrozole, letrozole)

or

- Abemaciclib in combination with a non-steroidal aromatase inhibitor (anastrozole, letrozole)

or

- Ribociclib in combination with fulvestrant

or

– Abemaciclib in combination with fulvestrant

or

– Palbociclib in combination with fulvestrant

**Extent and probability of the additional benefit of palbociclib in combination with letrozole compared to the appropriate comparator therapy:**

An additional benefit is not proven.

**Study results according to endpoints:**[1]

a1) First-line treatment of postmenopausal patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer

No complete data available.

**Summary of results for relevant clinical endpoints**

| Endpoint category | Direction of effect/ risk of bias | Summary |
|---|---|---|
| Mortality | n.c. | There are no assessable data. |
| Morbidity | n.c. | There are no assessable data. |
| Health-related quality of life | n.c. | There are no assessable data. |
| Side effects | n.c. | There are no assessable data. |
| Explanations:<br>↑: statistically significant and relevant positive effect with low/unclear reliability of data<br>↓: statistically significant and relevant negative effect with low/unclear reliability of data<br>↑↑: statistically significant and relevant positive effect with high reliability of data<br>↓↓: statistically significant and relevant negative effect with high reliability of data<br>↔: no statistically significant or relevant difference<br>∅: There are no usable data for the benefit assessment.<br>n.c.: not calculable | | |

"

**3. The findings under "2. Number of patients or demarcation of patient groups eligible for treatment" regarding the patient population "a1)" is adopted as follows:**

"

a1) First-line treatment of postmenopausal patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer

approx. 7,400 to 34,790 patients

"

**4. The findings under "3. Requirements for a quality-assured application" are adopted as follows:**

"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 Ibrance (active ingredient: palbociclib) at the following publicly accessible link (last access: 22 September 2022):

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

[1] Data from the dossier assessment of the IQWiG (A22-66) and from the addendum (A22-120), unless otherwise indicated.

Treatment with palbociclib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology, obstetrics and gynaecology, and specialists participating in the Oncology Agreement who are experienced in the treatment of patients with locally advanced or metastatic breast cancer.

**5. Under "4. Treatment costs", the findings on the annual treatment costs under "a1)" are adopted as follows:**

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

a1) First-line treatment of postmenopausal patients with HR-positive, HER2-negative, locally advanced or metastatic breast cancer

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Medicinal product to be assessed: | |
| *Palbociclib in combination with aromatase inhibitor* | |
| Palbociclib | € 30,196.27 |
| Anastrozole | € 190.09 |
| Letrozole | € 170.00 |
| Exemestane | € 425.37 |
| Total: | |
| Palbociclib + anastrozole | € 30,386.36 |
| Palbociclib + letrozole | € 30,366.27 |
| Palbociclib + exemestane | € 30,621.64 |
| Appropriate comparator therapy: | |
| *Non-steroidal aromatase inhibitors* | |
| Anastrozole | € 190.09 |
| Letrozole | € 170.00 |
| *Fulvestrant* | |
| Fulvestrant | € 4,419.35 |
| *Tamoxifen* | |
| Tamoxifen | € 72.20 |
| *Ribociclib in combination with a non-steroidal aromatase inhibitor (anastrozole, letrozole)* | |
| Ribociclib | € 29,658.81 |
| Anastrozole | € 190.09 |
| Letrozole | € 170.00 |
| Total | |
| Ribociclib + anastrozole | € 29,848.90 |
| Ribociclib + letrozole | € 29,828.81 |
| *Abemaciclib in combination with a non-steroidal aromatase inhibitor (anastrozole, letrozole)* | |

| Designation of the therapy | Annual treatment costs/ patient |
|---|---|
| Abemaciclib | € 23,637.40 |
| Anastrozole | € 190.09 |
| Letrozole | € 170.00 |
| Total | |
| Abemaciclib + anastrozole | € 23,827.49 |
| Abemaciclib + letrozole | € 23,807.40 |
| *Ribociclib in combination with fulvestrant* | |
| Ribociclib | € 29,658.81 |
| Fulvestrant | € 4,759.30 |
| Total | |
| Ribociclib + fulvestrant | € 34,418.11 |
| *Abemaciclib in combination with fulvestrant* | |
| Abemaciclib | € 23,637.40 |
| Fulvestrant | € 4,419.35 |
| Total | |
| Abemaciclib + fulvestrant | € 28,056.75 |
| *Palbociclib in combination with fulvestrant* | |
| Palbociclib | € 30,196.27 |
| Fulvestrant | € 4,759.30 |
| Total | |
| Palbociclib + fulvestrant | € 34,995.57 |

Costs after deduction of statutory rebates (LAUER-TAXE®) as last revised: 15 November 2022)

Costs for additionally required SHI services: not applicable".



**6. 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 Palbociclib**

Medicinal products with new active ingredients pursuant to Section 35a, paragraph 3, sentence 4 SGB V are medicinal products with the following new active ingredients which, on the basis of the marketing authorisation under Medicinal Products Act, can be used in a combination therapy with palbociclib for the first-line treatment of postmenopausal patients with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer:

- No active ingredient that can be used in a combination therapy that fulfils the requirements of Section 35a, paragraph 3, sentence 4 SGB V.

**II. The resolution will enter into force on the day of its publication on the website of the G-BA on 15 December 2022.**

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

Berlin, 15 December 2022

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

Prof. Hecken