

# 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 and  
Annex XIIa – Combinations of Medicinal Products with New  
Active Ingredients according to Section 35a SGB V

Inavolisib (breast cancer, PIK3CA-mutated, ER+, HER2-, locally  
advanced or metastatic, recurrence < 12 months after  
adjuvant endocrine therapy, combination with palbociclib  
and fulvestrant)

of 19 February 2026

At their session on 19 February 2026, 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 shall be amended in alphabetical order to include the active ingredient  
Inavolisib as follows:**

## **Inavolisib**

Resolution of: 19 February 2026

Entry into force on: 19 February 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

### **Therapeutic indication (according to the marketing authorisation of 18 July 2025):**

Itovebi, in combination with palbociclib and fulvestrant, is indicated for the treatment of adult patients with PIK3CA-mutated, oestrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment.

There should be an interval of at least 12 months between discontinuation of the CDK4/6 inhibitor and detection of recurrence in patients who have previously been treated with a CDK4/6 inhibitor as part of (neo)adjuvant treatment.

In pre/perimenopausal women and in men, endocrine therapy should be combined with an LHRH agonist (LHRH = luteinising hormone-releasing hormone).

### **Therapeutic indication of the resolution (resolution of 19 February 2026):**

See therapeutic indication according to marketing authorisation.

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

- a) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

##### **Appropriate comparator therapy:**

- Tamoxifen (only for premenopausal patients who have not received tamoxifen in previous (neo-)adjuvant endocrine therapy; only for postmenopausal patients if aromatase inhibitors are unsuitable)

*or*

- letrozole

*or*

- exemestane (only for patients with progression after anti-oestrogen treatment)

*or*

- anastrozole

*or*

- fulvestrant

*or*

- everolimus in combination with exemestane (only for patients without symptomatic visceral metastasis, followed by progression after a non-steroidal aromatase inhibitor)

*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*

- palbociclib 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 inavolisib in combination with palbociclib and fulvestrant compared with palbociclib and fulvestrant:**

- a1) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment, who have not received prior treatment with a CDK4/6 inhibitor as part of (neo)adjuvant treatment

Hint for a considerable additional benefit

- a2) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment, who have received prior treatment with a CDK4/6 inhibitor as part of (neo)adjuvant treatment

An additional benefit is not proven.

- b) Men with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

**Appropriate comparator therapy:**

- Tamoxifen

or

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

**Extent and probability of the additional benefit of inavolisib in combination with palbociclib and fulvestrant compared with palbociclib and fulvestrant:**

An additional benefit is not proven.

**Study results according to endpoints:<sup>1</sup>**

- a1) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment, who have not received prior treatment with a CDK4/6 inhibitor as part of (neo)adjuvant treatment

**Summary of results for relevant clinical endpoints**

| Endpoint category  | Direction of effect/<br>risk of bias | Summary   |
|--|--------------------------------------|---|
| Mortality  | ↑                                    | Advantage in overall survival   |
| Morbidity  | n.a.                                 | There are no assessable data.   |
| Health-related quality of life   | n.a.                                 | There are no assessable data.   |
| Side effects   | ↓                                    | Disadvantage in the endpoint: therapy discontinuation due to adverse events |
| 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>∅: No data available.<br>n.a.: not assessable |                                      |   |

<sup>1</sup> Data from the dossier assessment of the Institute for Quality and Efficiency in Health Care (IQWiG) (A25-104), unless otherwise indicated.

INAVO120 study: Inavolisib + palbociclib + fulvestrant vs palbociclib + fulvestrant

**Mortality**

| Endpoint  | Inavolisib + palbociclib + fulvestrant |   | Palbociclib + fulvestrant |   | Intervention vs control  |
|---|--|---|---------------------------|---|--|
|   | N                                      | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | N                         | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | Hazard ratio <sup>b</sup> [95% CI] <sup>c</sup><br>p value <sup>d</sup><br>Absolute difference (AD) <sup>a</sup> |
| <b>Overall survival</b>                         |  |   |                           |   |  |
|   | 161                                    | 34.0 [28.4; 44.8]<br>72 (44.7)  | 164                       | 27.0 [22.8; 38.7]<br>82 (50.0)  | 0.67 [0.48; 0.94]<br>0.019<br>AD = 7.0 months  |
| Effect modification by the "age" characteristic |  |   |                           |   |  |
| < 65 years                                      | 136                                    | 36.0 [29.5; n.c.]<br>59 (43.4)  | 130                       | 26.8 [22.3; 36.0]<br>68 (52.3)  | 0.65 [0.46; 0.92]<br>0.015<br>AD = 9.2 months  |
| ≥ 65 years                                      | 25                                     | 14.4 [9.1; n.c.]<br>13 (52.0)   | 34                        | n.r. [16.6; n.c.]<br>14 (41.2)  | 1.65 [0.77; 3.51]<br>0.191   |
| Interaction <sup>f</sup> : 0.033                |  |   |                           |   |  |

**Morbidity**

| Endpoint   | Inavolisib + palbociclib + fulvestrant |   | Palbociclib + fulvestrant |   | Intervention vs control  |
|--|--|---|---------------------------|---|--|
|  | N                                      | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | N                         | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | Hazard ratio <sup>b</sup> [95% CI] <sup>c</sup><br>p value <sup>d</sup><br>Absolute difference (AD) <sup>a</sup> |
| <b>Progression-free survival (PFS)<sup>e</sup></b> |  |   |                           |   |  |
|  | 161                                    | 17.2 [11.6; 22.2]<br>103 (64.0)   | 164                       | 7.3 [5.9; 9.2]<br>141 (86.0)  | 0.42 [0.32; 0.55]<br>0.0001<br>AD = 9.9 months   |
| <b>Symptomatic skeletal events</b>                 |  |   |                           |   |  |
| No suitable data available.                        |  |   |                           |   |  |
| Endpoint   | Inavolisib + palbociclib + fulvestrant |   | Palbociclib + fulvestrant |   | Intervention vs control  |

|  | N | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | N | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | Hazard ratio <sup>b</sup> [95% CI] <sup>c</sup><br>p value <sup>d</sup><br>Absolute difference (AD) <sup>a</sup> |
|--|---|---|---|---|--|
| <b>Symptomatology</b>                                |   |   |   |   |  |
| <i>EORTC QLQ-C30, EORTC QLQ-BR23, symptom scales</i> |   |   |   |   |  |
| No suitable data available.                          |   |   |   |   |  |
| <b>Worst pain</b>                                    |   |   |   |   |  |
| <i>BPI-SF item 3</i>                                 |   |   |   |   |  |
| No suitable data available.                          |   |   |   |   |  |
| <b>Health status</b>                                 |   |   |   |   |  |
| <i>EQ-5D VAS</i>                                     |   |   |   |   |  |
| No suitable data available.                          |   |   |   |   |  |

#### Health-related quality of life

| Endpoint  | Inavolisib + palbociclib + fulvestrant |   | Palbociclib + fulvestrant |   | Intervention vs control |
|---|--|---|---------------------------|---|-------------------------|
|   | N                                      | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | N                         | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> |                         |
| <i>EORTC QLQ-C30, EORTC QLQ-BR23, functional scales</i> |  |   |                           |   |                         |
| No suitable data available.                             |  |   |                           |   |                         |

## Side effects

| Endpoint   | Inavolisib + palbociclib + fulvestrant |   | Palbociclib + fulvestrant |   | Intervention vs control  |
|--|--|---|---------------------------|---|--|
|  | N                                      | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | N                         | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | Hazard ratio <sup>b</sup> [95% CI] <sup>c</sup><br>p value <sup>d</sup><br>Absolute difference (AD) <sup>a</sup> |
| <b>Adverse events in total</b>                                   |  |   |                           |   |  |
|  | 161                                    | n.d.<br>161 (100.0)   | 163                       | n.d.<br>163 (100.0)   | –  |
| <b>Serious adverse events (SAEs)</b>                             |  |   |                           |   |  |
|  | 161                                    | n.d.<br>44 (27.3)   | 163                       | n.d.<br>22 (13.5)   | 1.64<br>[0.98; 2.74]<br>0.058  |
| <b>Severe adverse events (CTCAE grade 3 or 4)</b>                |  |   |                           |   |  |
|  | 161                                    | n.d.<br>148 (91.9)  | 163                       | n.d.<br>140 (85.9)  | 1.14<br>[0.90; 1.44]<br>0.276  |
| <b>Therapy discontinuation due to adverse events<sup>e</sup></b> |  |   |                           |   |  |
|  | 161                                    | n.d.<br>14 (8.7)  | 163                       | n.d.<br>1 (0.6)   | 12.72<br>[1.67; 96.95]<br>0.002  |
| PRO-CTCAE  | No suitable data available.            |   |                           |   |  |
| <b>Specific adverse events</b>                                   |  |   |                           |   |  |
| Stomatitis (PT, AEs)   | 161                                    | n.d.<br>57 (35.4)   | 163                       | n.d.<br>30 (18.4)   | 2.07<br>[1.33; 3.22]<br>0.001  |
| Hyperglycaemia (PT, severe AEs)                                  | 161                                    | n.d.<br>9 (5.6)   | 163                       | n.d.<br>0 (0)   | –; 0.003   |
| Loss of appetite (PT, AEs)                                       | 161                                    | n.d.<br>44 (27.3)   | 163                       | n.d.<br>18 (11)   | 2.30<br>[1.33; 3.99]<br>0.002  |
| Non-infectious diarrhoea (SMQ, AEs)                              | 161                                    | n.d.<br>84 (52.2)   | 163                       | n.d.<br>26 (16)   | 3.73<br>[2.40; 5.79]<br>< 0.001  |
| Thrombocytopenia (PT, severe AEs)                                | 161                                    | n.d.<br>14 (8.7)  | 163                       | n.d.<br>5 (3.1)   | 2.95<br>[1.06; 8.20]<br>0.029  |
| Endpoint   | Inavolisib + palbociclib + fulvestrant |   | Palbociclib + fulvestrant |   | Intervention vs control  |

|  | N   | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | N   | Median survival time in months [95% CI]<br><i>Patients with event n (%)</i> | Hazard ratio <sup>b</sup> [95% CI] <sup>c</sup><br>p value <sup>d</sup><br>Absolute difference (AD) <sup>a</sup> |
|--|-----|---|-----|---|--|
| Metabolism and nutrition disorders (SOC, severe AEs) | 161 | n.d.<br>20 (12.4)   | 163 | n.d.<br>5 (3.1)   | 3.64<br>[1.36; 9.75]<br>0.006  |
| Gastrointestinal disorders (SOC, severe AEs)         | 161 | n.d.<br>18 (11.2)   | 163 | n.d.<br>4 (2.5)   | 4.12<br>[1.39; 12.21]<br>0.006   |

<sup>a</sup> Indication of absolute difference (AD) only in case of statistically significant difference; own calculation

<sup>b</sup> HR: COX proportional hazards model

<sup>c</sup> CI: COX proportional hazards model

<sup>d</sup> p value: log-rank test

<sup>e</sup> Discontinuation of any components of the study medication

<sup>f</sup> Interaction testing: Cox proportional hazards model with corresponding interaction term; likelihood ratio test

<sup>g</sup> Information provided by the pharmaceutical company in the dossier

Abbreviations used:

AD = absolute difference; BPI-SF = Brief Pain Inventory – Short Form; CTCAE = Common Terminology Criteria for Adverse Events; EORTC = European Organisation for Research and Treatment of Cancer; HR = hazard ratio; n.d.: no data available; CI = confidence interval; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; PRO-CTCAE: Patient Reported Outcome – CTCAE; PT = preferred term; QLQ-BR23 = Quality of Life Questionnaire-Breast Cancer 23; QLQ-C30 = Quality of Life Questionnaire-Core 30; RCT = randomised controlled trial; SMQ = standardised MedDRA query; SOC = system organ class; SAE = serious adverse event; AE = adverse event; VAS = visual analogue scale; vs = versus

a2) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment, who have received prior treatment with a CDK4/6 inhibitor as part of (neo)adjuvant treatment

| Endpoint category  | Direction of effect/<br>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:<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>∅: No data available.<br>n.a.: not assessable |                                      |                               |

b) Men with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

| Endpoint category  | Direction of effect/<br>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:<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>∅: No data available.<br>n.a.: not assessable |                                      |                               |

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

- a) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

Approx. 860 to 3,590 patients

- b) Men with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

Approx. 8 to 35 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 Itovebi (active ingredient: inavolisib) at the following publicly accessible link (last access: 18 November 2025):

[https://www.ema.europa.eu/en/documents/product-information/itovebi-epar-product-information\\_en.pdf](https://www.ema.europa.eu/en/documents/product-information/itovebi-epar-product-information_en.pdf)

Treatment with inavolisib should only be initiated and monitored by specialists in internal medicine, haematology, and oncology who are experienced in the treatment of patients with breast cancer, as well as specialists in obstetrics and gynaecology, and other specialists from other specialist groups participating in the Oncology Agreement.

Patients with ER-positive, HER2-negative, locally advanced or metastatic breast cancer should be selected for treatment with inavolisib based on the presence of one or more PIK3CA mutations in a tumour or plasma sample. Detection of PIK3CA mutation(s) must be performed using a CE-marked in vitro diagnostic (IVD) device with the appropriate intended use. If a CE-marked IVD is not available, an alternative validated test must be used.

#### 4. Treatment costs

##### Annual treatment costs:

- a) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

| Designation of the therapy   | Annual treatment costs/ patient |
|--|---------------------------------|
| <b>Medicinal product to be assessed:</b>   |                                 |
| Inavolisib   | € 190,025.00                    |
| Palbociclib  | € 23,124.01                     |
| fulvestrant  | € 4,505.48                      |
| Total:   | € 217,654.49                    |
| <b>Plus GnRH analogue, if applicable</b>   |                                 |
| Goserelin  | € 2,783.47                      |
| Leuprorelin  | € 1,906.92                      |
| <b>Appropriate comparator therapy:</b>   |                                 |
| <i>Anti-oestrogens</i>   |                                 |
| Tamoxifen  | € 91.10                         |
| fulvestrant  | € 4,183.66                      |
| <i>Non-steroidal aromatase inhibitors</i>  |                                 |
| Anastrozole  | € 143.63                        |
| Letrozole  | € 170.12                        |
| <i>Steroidal aromatase inhibitors</i>  |                                 |
| Exemestane   | € 425.48                        |
| <i>Ribociclib in combination with a non-steroidal aromatase inhibitor (anastrozole, letrozole)</i> |                                 |
| Ribociclib   | € 29,658.94                     |
| Anastrozole  | € 143.63                        |
| Letrozole  | € 170.12                        |
| Ribociclib + anastrozole<br>Total:   | € 29,802.57                     |
| Ribociclib + letrozole<br>Total:   | € 29,829.06                     |
| <b>Plus GnRH analogue, if applicable</b>   |                                 |
| Goserelin  | € 2,783.47                      |

| Designation of the therapy  | Annual treatment costs/ patient |
|---|---------------------------------|
| Leuprorelin   | € 1,906.92                      |
| <i>Abemaciclib in combination with a non-steroidal aromatase inhibitor (anastrozole, letrozole)</i> |                                 |
| Abemaciclib   | € 24,868.93                     |
| Anastrozole   | € 143.63                        |
| Letrozole   | € 170.12                        |
| Abemaciclib + anastrozole<br>Total:   | € 25,012.56                     |
| Abemaciclib + letrozole<br>Total:   | € 25,039.05                     |
| Plus GnRH analogue, if applicable   |                                 |
| Goserelin   | € 2,783.47                      |
| Leuprorelin   | € 1,906.92                      |
| <i>Palbociclib in combination with a non-steroidal aromatase inhibitor (anastrozole, letrozole)</i> |                                 |
| Palbociclib   | € 23,124.01                     |
| Anastrozole   | € 143.63                        |
| Letrozole   | € 170.12                        |
| Palbociclib + anastrozole<br>Total:   | € 23,267.64                     |
| Palbociclib + letrozole<br>Total:   | € 23,294.13                     |
| Plus GnRH analogue, if applicable   |                                 |
| Goserelin   | € 2,783.47                      |
| Leuprorelin   | € 1,906.92                      |
| <i>Ribociclib in combination with fulvestrant</i>   |                                 |
| Ribociclib  | € 29,658.94                     |
| fulvestrant   | € 4,505.48                      |
| Total:  | € 34,164.42                     |
| Plus GnRH analogue, if applicable   |                                 |
| Goserelin   | € 2,783.47                      |
| Leuprorelin   | € 1,906.92                      |
| <i>Abemaciclib in combination with fulvestrant</i>  |                                 |
| Abemaciclib   | € 24,868.93                     |
| fulvestrant   | € 4,183.66                      |

| Designation of the therapy                         | Annual treatment costs/ patient |
|--|---------------------------------|
| Total:   | € 29,052.59                     |
| Plus GnRH analogue, if applicable                  |                                 |
| Goserelin  | € 2,783.47                      |
| Leuprorelin  | € 1,906.92                      |
| <i>Palbociclib in combination with fulvestrant</i> |                                 |
| Palbociclib  | € 23,124.01                     |
| fulvestrant  | € 4,505.48                      |
| Total:   | € 27,629.49                     |
| Plus GnRH analogue, if applicable                  |                                 |
| Goserelin  | € 2,783.47                      |
| Leuprorelin  | € 1,906.92                      |
| Everolimus in combination with exemestane          |                                 |
| Everolimus   | € 4,848.17                      |
| Exemestane   | € 425.48                        |
| Total:   | € 5,273.65                      |

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 December 2025)

- b) Men with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

| Designation of the therapy        | Annual treatment costs/ patient |
|-----------------------------------|---------------------------------|
| Medicinal product to be assessed: |                                 |
| Inavolisib                        | € 190,025.00                    |
| Palbociclib                       | € 19,877.52                     |
| fulvestrant                       | € 4,505.48                      |
| Total:                            | € 214,408.00                    |
| Plus GnRH analogue, if applicable |                                 |
| Goserelin                         | € 2,783.47                      |
| Leuprorelin                       | € 1,906.92                      |
| Appropriate comparator therapy:   |                                 |
| <i>Anti-oestrogens</i>            |                                 |

| Designation of the therapy  | Annual treatment costs/ patient |
|---|---------------------------------|
| Tamoxifen   | € 91.10                         |
| <i>Palbociclib in combination with a non-steroidal aromatase inhibitor (anastrozole, letrozole)</i> |                                 |
| Palbociclib   | € 23,124.01                     |
| Anastrozole   | € 143.63                        |
| Letrozole   | € 170.12                        |
| Palbociclib + anastrozole<br>Total:   | € 23,267.64                     |
| Palbociclib + letrozole<br>Total:   | € 23,294.13                     |

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 December 2025)

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:

a1) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment, who have not received prior treatment with a CDK4/6 inhibitor as part of (neo)adjuvant treatment

The following medicinal products with new active ingredients that can be used in a combination therapy with the assessed medicinal product in the therapeutic indication of the present resolution on the basis of the marketing authorisation under Medicinal Products Act are excluded from the designation, as the G-BA have identified at least considerable additional benefit for the combination with the assessed medicinal product in the present resolution:

- Palbociclib (Ibrance)

- a2) Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment, who have received prior treatment with a CDK4/6 inhibitor as part of (neo)adjuvant treatment

The following medicinal products with new active ingredients that can be used in a combination therapy with inavolisib in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

- Palbociclib (Ibrance)

- b) Men with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

The following medicinal products with new active ingredients that can be used in a combination therapy with inavolisib in the therapeutic indication of the resolution on the basis of the marketing authorisation under Medicinal Products Act are named (active ingredients and invented names) in accordance with Section 35a, paragraph 3, sentence 4 SGB V:

- Palbociclib (Ibrance)

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.

## **6. Percentage of study participants at study sites within the scope of SGB V in accordance with Section 35a, paragraph 3, sentence 5 SGB V**

The medicinal product inavolisib is a medicinal product placed on the market from 1 January 2025.

The percentage of study participants in the clinical studies of the medicinal product conducted or commissioned by the pharmaceutical company in the therapeutic indication to be assessed who participated at study sites within the scope of SGB V (German Social Security Code) is < 5% of the total number of study participants.

The clinical studies of the medicinal product in the therapeutic indication to be assessed were therefore not conducted to a relevant extent within the scope of SGB V.

**II. In Annex XIIa of the Pharmaceuticals Directive, the following information shall be added in alphabetical order:**

"Active ingredient of the assessed medicinal product

Inavolisib

Resolution according to Section 35a paragraph 3 SGB V from

19 February 2026

Therapeutic indication of the resolution

Itovebi, in combination with palbociclib and fulvestrant, is indicated for the treatment of adult patients with PIK3CA-mutated, oestrogen receptor (ER)-positive, HER2-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment.

There should be an interval of at least 12 months between discontinuation of the CDK4/6 inhibitor and detection of recurrence in patients who have previously been treated with a CDK4/6 inhibitor as part of (neo)adjuvant treatment.

In pre/perimenopausal women and in men, endocrine therapy should be combined with an LHRH agonist (LHRH = luteinising hormone-releasing hormone).

Patient group a2)

Women with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment, who have received prior treatment with a CDK4/6 inhibitor as part of (neo)adjuvant treatment

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names<sup>2</sup>)

Palbociclib (Ibrance)

Period of validity of the designation (since... or from... to)

Since 19 February 2026

Patient group b

Men with PIK3CA-mutated, hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, locally advanced or metastatic breast cancer, following recurrence on or within 12 months of completing adjuvant endocrine treatment

Naming of medicinal products with new active ingredients according to Section 35a, paragraph 3, sentence 4 SGB V (active ingredients and invented names<sup>2</sup>)

Palbociclib (Ibrance)

Period of validity of the designation (since... or from... to)

Since 19 February 2026

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.

**III. The resolution will enter into force on the day of its publication on the website of the G-BA on 19 February 2026.**

The justification to this resolution will be published on the G-BA website at [www.g-ba.de](http://www.g-ba.de).

Berlin, 19 February 2026

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

Prof. Hecken