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

Abemaciclib (reassessment after the deadline: breast cancer, HR+, HER2-, early at high risk of recurrence, adjuvant treatment, combination with endocrine therapy)

From 20 August 2026

At their session on 20 August 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. In Annex XII, the information on the active ingredient abemaciclib in the version of the resolution of 20 October 2022 (BAnz AT 08.12.2022 B5), as amended by the resolution of 8 November 2022 and the resolution of 6 March 2025, shall be amended as follows:

1. The information

   "Resolution of: 20 October 2022/ 8 November 2022/ 6 March 2025
   Entry into force on: 20 October 2022/ 10 November 2022/ 6 March 2025
   BAnz AT 08.12.2022 B5/ BAnz AT 02.01.2023 B2/ BAnz AT 25.03.2025 B2
   Valid until: Patient populations a1) and a2) limited until 1 July 2026"

   is replaced by the following information:

   "Resolution of: 20 October 2022/ 8 November 2022/ 6 March 2025/ 20 August 2026
   Entry into force on: 20 October 2022/ 10 November 2022/ 6 March 2025/ 20 August 2026
   BAnz AT 08.12.2022 B5/ BAnz AT 02.01.2023 B2/ BAnz AT 25.03.2025 B2/ BAnz AT TT. MM YYYY Bx
   Valid until: indefinite"

2. Before number 1 "Additional benefit of the medicinal product in relation to the appropriate comparator therapy" and after the information "**Therapeutic indication of the resolution (resolution of 20 October 2022):** See new therapeutic indication according to the marketing authorisation.", the following information is added:

Therapeutic indication of the resolution (resolution of 20 August 2026):

Verzenios in combination with endocrine therapy is indicated for the adjuvant treatment of premenopausal and postmenopausal women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative, node-positive early breast cancer at high risk of recurrence.

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

3. In number 1 "**Additional benefit of the medicinal product in relation to the appropriate comparator therapy**", the information is amended as follows:

a) Following the information "- Tamoxifen (if applicable, with additional ovarian function suppression)", the information
"
or
- olaparib as monotherapy or in combination with endocrine therapy (only female patients with germline BRCA1/2-mutations are eligible)
or
- an aromatase inhibitor (anastrozole or letrozole or exemestane) in combination with ovarian function suppression (exemestane only in combination with triptorelin)
or
- ribociclib in combination with an aromatase inhibitor
"
is inserted.

b) After the statement "- An aromatase inhibitor (anastrozole or exemestane) in sequence after tamoxifen", the information
"
or
- olaparib as monotherapy or in combination with endocrine therapy (only female patients with germline BRCA1/2-mutations are eligible)
or
- ribociclib in combination with an aromatase inhibitor
"
is inserted.

c) The information after the heading "**Study results according to endpoints:[1]**" is amended as follows:

aa) In footnote 1, the information "Data from the dossier assessment of the IQWiG (A22-51) and from the addendum (A22-96), unless otherwise indicated." is replaced by the information
"Data from the dossier assessment of the IQWiG (A22-51 and A26-17) and from the addendum (A22-96 and A26-83), unless otherwise indicated."
.

bb) The information following the heading "a1) Premenopausal women with hormone receptor-positive, HER2-negative early breast cancer at high risk of recurrence" is replaced by the following information:

"

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↑	Advantage in overall survival.
Morbidity	↑	Advantage in avoiding recurrences (recurrence rate and disease-free survival).
Health-related quality of life	↔	No relevant difference for the benefit assessment.
Side effects	↓↓	Disadvantages in the endpoints of SAEs, severe AEs (CTCAE grade ≥ 3) and therapy discontinuation due to AEs.
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		

MONARCH-E study:

- Ongoing, open-label, randomised controlled trial
- Abemaciclib in combination with endocrine therapy vs endocrine therapy
- Relevant to cohort 1: high risk of recurrence defined as ≥ 4 positive axillary lymph nodes (pALN) or 1 to 3 pALN in the presence of an additional grade 3 tumour and/or a tumour size ≥ 5 cm (corresponding to stage IIA to IIIC at the time of diagnosis).
- Relevant sub-population: premenopausal women

Mortality

Endpoint	Abemaciclib in combination with endocrine therapy		Endocrine therapy		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value[a]
Overall survival					
	864	n.r. *72 (8.3)*	851	n.r. *101 (11.9)*	0.69 [0.51; 0.93]; 0.014

Morbidity

Endpoint	Abemaciclib in combination with endocrine therapy		Endocrine therapy		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI]

					p value[b] Absolute difference (AD)[c]
Failure of the curative therapeutic approach					
Recurrence rate	864	154 (17.8)	851	228 (26.8)	0.67 [0.56; 0.80]; < 0.001 AD = 9.0%
Local breast cancer recurrence	864	9 (1.0)	851	18 (2.1)	-
Regional invasive breast cancer recurrence	864	7 (0.8)	851	9 (1.1)	-
Distant recurrence	864	124 (14.4)	851	182 (21.4)	-
Contralateral invasive breast cancer	864	6 (0.7)	851	11 (1.3)	-
Secondary primary cancer (not breast cancer)	864	8 (0.9)	851	9 (1.1)	-
Death	864	2 (0.2)	851	6 (0.7)	-
Disease-free survival	864	154 (17.8) Median time to event: n.r.	851	228 (26.8) Median time to event: n.r.	HR: 0.61 [0.50; 0.75]; < 0.001

Endpoint	**Abemaciclib in combination with endocrine therapy**			**Endocrine therapy**			Intervention vs control
	N	Values at the start of the study MV (SD)	Change MV[d] (SE)	N	Values at the start of the study MV (SD)	Change MV[d] (SE)	MD [95% CI]; p value[d]; SMD [95% CI]
Symptomatology (FACIT-Fatigue)[e]							
	754	40.7 (9.1)	-0.7 (0.2)	738	40.3 (9.1)	0.5 (0.2)	-1.23 [-1.86; -0.60]; < 0.001; -0.20 [-0.30; -0.10]
Health status (EQ-5D VAS)[e]							
	757	77.9 (15.2)	2.0 (0.4)	739	78.4 (15.8)	2.5 (0.4)	-0.47 [-1.52; 0.57]; 0.375; -0.05 [-0.15; 0.06]

Health-related quality of life

Endpoint	Abemaciclib in combination with endocrine therapy			Endocrine therapy			Intervention vs control
	N	Values at the start of the study MV (SD)	Change MV[d] (SE)	N	Values at the start of the study MV (SD)	Change MV[d] (SE)	MD [95% CI]; p value[d]; SMD [95% CI]
FACT-B (total score)[g]							
	770	107.8 (17.7)	-1.5 (0.5)	751	106.4 (18.2)	0.8 (0.5)	-2.34 [-3.60; -1.08] < 0.001; -0.19 [-0.29; -0.09]

Side effects

Endpoint	Abemaciclib in combination with endocrine therapy		Endocrine therapy		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value[b] Absolute difference (AD)[c]
Total adverse events (presented additionally)					
	863	848 (98.3)	852	756 (88.7)	-
Serious adverse events (SAEs)					
	863	118 (13.7)	852	77 (9.0)	1.51 [1.15; 1.98]; 0.003 AD = 4.7%
Severe adverse events (CTCAE grade 3 or 4)					
	863	420 (48.7)	852	144 (16.9)	2.88 [2.44; 3.39]; < 0.001 AD = 31.8%
Therapy discontinuation due to adverse events					
	863	101 (11.7)	852	7 (0.8)	14.24 [6.66; 30.46]; < 0.001 AD = 10.9%
Specific adverse events					
Neutropenia (PT, severe AEs)	863	66 (7.6)	852	6 (0.7)	10.86 [4.73; 24.91]; < 0.001 AD = 6.9%
Eye disorders (SOC, AE)	863	122 (14.1)	852	61 (7.2)	1.97 [1.47; 2.65]; < 0.001 AD = 6.9%

Skin and subcutaneous tissue disorders (SOC, AE)	863	347 (40.2)	852	189 (22.2)	1.81 [1.56; 2.11]; < 0.001 AD = 18.0%
Gastrointestinal disorders (SOC, severe AEs)	863	68 (7.9)	852	8 (0.9)	8.39 [4.06; 17.35]; < 0.001 AD = 7.0%
Diarrhoea (PT, severe AEs)	863	49 (5.7)	852	3 (0.4)	16.13 [5.05; 51.53]; < 0.001 AD = 5.3%
General disorders and administration site conditions (SOC, severe AEs)	863	21 (2.4)	852	8 (0.9)	2.59 [1.15; 5.82]; 0.017 AD = 1.5%
Hepatobiliary disorders (SOC, severe AEs)	863	11 (1.3)	852	3 (0.4)	3.62 [1.01; 12.93]; 0.035 AD = 0.9%
Physical examinations (SOC, severe AEs)	863	181 (21.0)	852	21 (2.5)	8.51 [5.47; 13.24]; < 0.001 AD = 18.5%
Metabolism and nutrition disorders (SOC, severe AEs)	863	19 (2.2)	852	7 (0.8)	2.68 [1.13; 6.34]; 0.020 AD = 1.4%
Genital and mammary gland disorders (SOC, severe AEs)	863	7 (0.8)	852	17 (2.0)	0.41 [0.17; 0.98]; 0.039 AD = 1.2%
Respiratory, thoracic and mediastinal disorders (SOC, severe AEs)	863	14 (1.6)	852	3 (0.4)	4.61 [1.33; 15.97]; 0.008 AD = 1.2%

[a] p value: log-rank test. No data on the model available; presumably an unstratified Cox proportional hazards model
[b] IQWiG's own calculation, unconditional exact test (CSZ method according to Martin Andrés et al.[1])
[c] Information on absolute difference (AD) only in case of statistically significant difference; own calculation
[d] MMRM with the variables: Value at the start of the study, treatment, visit, treatment*visit.
[e] Higher (increasing) values mean minor symptomatology; positive effects mean an advantage for the intervention (scale range 0 to 52).
[f] Higher (increasing) values mean better health status; positive effects mean an advantage for the intervention (scale range 0 to 100).
[g] Higher (increasing) values mean better health-related quality of life; positive effects mean an advantage for the intervention (scale range 0 to 148).

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; FACT-B = Functional Assessment of Cancer Therapy – Breast; FACIT-Fatigue = Functional Assessment of Chronic Illness Therapy – Fatigue; HR = hazard ratio; CI = confidence interval; MMRM = mixed model with repeated measures; MV = mean value; MD = mean difference; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; RR = relative risk; SD = standard deviation; SE = standard error; SMD = standardised mean difference; SOC = system organ class; VAS = visual analogue scale; vs = versus

[1] Martín Andrés A, Silva Mato A. Choosing the optimal unconditional test for comparing two independent proportions. Computat Stat Data Anal 1994; 17(5): 555-574. https://dx.doi.org/10.1016/0167-9473(94)90148-1.

"

cc) The information following the heading "a2) Postmenopausal women with hormone receptor-positive, HER2-negative early breast cancer at high risk of recurrence" is replaced by the following information:

"

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	↔	No relevant difference for the benefit assessment.
Morbidity	↑	Advantage in avoiding recurrences (recurrence rate and disease-free survival).
Health-related quality of life	↔	No relevant difference for the benefit assessment.
Side effects	↓↓	Disadvantages in the endpoints of SAEs, severe AEs (CTCAE grade ≥ 3) and therapy discontinuation due to AEs.
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		

MONARCH-E study:

- Ongoing, open-label, randomised controlled trial
- Abemaciclib in combination with endocrine therapy vs endocrine therapy
- Relevant to cohort 1: high risk of recurrence defined as ≥ 4 positive axillary lymph nodes (pALN) or 1 to 3 pALN in the presence of an additional grade 3 tumour and/or a tumour size ≥ 5 cm (corresponding to stage IIA to IIIC at the time of diagnosis).
- Relevant sub-population: postmenopausal women

Mortality

Endpoint	Abemaciclib in combination with endocrine therapy		Endocrine therapy		Intervention vs control
	N	Median survival time in months [95% CI] *Patients with event n (%)*	N	Median survival time in months [95% CI] *Patients with event n (%)*	HR [95% CI] p value[a]
Overall survival					
	1,364	n.r. *185 (13.6)*	1,384	n.r. *220 (15.9)*	0.87 [0.71; 1.06]; 0.155

Morbidity

Endpoint	Abemaciclib in combination with endocrine therapy		Endocrine therapy		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value[b] Absolute difference (AD)[c]
Failure of the curative therapeutic approach					
Recurrence rate	1,364	303 (22.2)	1,384	398 (28.8)	0.77 [0.68; 0.88]; < 0.001 AD = 6.6%
Local breast cancer recurrence	1,364	23 (1.7)	1,384	35 (2.5)	-
Regional invasive breast cancer recurrence	1,364	22 (1.6)	1,384	23 (1.7)	-
Distant recurrence	1,364	185 (13.6)	1,384	276 (19.9)	-
Contralateral invasive breast cancer	1,364	6 (< 1)	1,384	9 (< 1)	-
Secondary primary cancer (not breast cancer)	1,364	32 (2.3)	1,384	35 (2.5)	-
Death	1,364	43 (3.2)	1,384	26 (1.9)	-

Disease-free survival	1,364	303 (22.2) Median time to event: n.r.	1,384	398 (28.8) Median time to event: n.r.	HR: 0.76 [0.66; 0.89]; < 0.001

Endpoint	Abemaciclib in combination with endocrine therapy			Endocrine therapy			Intervention vs control
	N	Values at the start of the study MV (SD)	Change MV[d] (SE)	N	Values at the start of the study MV (SD)	Change MV[d] (SE)	MD [95% CI]; p value[d]; SMD [95% CI]
Symptomatology (FACIT-Fatigue)[e]							
	1,144	39.9 (9.6)	-1.0 (0.2)	1,169	39.3 (9.7)	0.3 (0.2)	-1.34 [-1.85; -0.84] < 0.001; -0.22 [-0.3; -0.13]
Health status (EQ-5D VAS)[f]							
	1,159	77.7 (16.6)	-0.1 (0.3)	1,188	78.0 (15.2)	1.2 (0.3)	-1.26 [-2.1; -0.43]; 0.003; -0.12 [-0.2; -0.04]

Health-related quality of life

Endpoint	Abemaciclib in combination with endocrine therapy			Endocrine therapy			Intervention vs control
	N	Values at the start of the study MV (SD)	Change MV[d] (SE)	N	Values at the start of the study MV (SD)	Change MV[d] (SE)	MD [95% CI]; p value[d]; SMD [95% CI]
FACT-B (total score)[g]							
	1,173	108.0 (18.4)	-1.9 (0.4)	1,209	107.4 (18.0)	-0.2 (0.4)	-1.71 [-2.68; -0.74] < 0.001; -0.14 [-0.22; -0.06]

Side effects

Endpoint	Abemaciclib in combination with endocrine therapy		Endocrine therapy		Intervention vs control
	N	Patients with event n (%)	N	Patients with event n (%)	RR [95% CI] p value[b] Absolute difference (AD)[c]
Total adverse events (presented additionally)					
	1,363	1,339 (98.2)	1,385	1,237 (89.3)	-

Serious adverse events (SAEs)					
	1,363	233 (17.1)	1,385	141 (10.2)	1.68 [1.38; 2.04]; < 0.001 AD = 6.9%

Severe adverse events (CTCAE grade 3 or 4)					
	1,363	694 (50.9)	1,385	254 (18.3)	2.78 [2.46; 3.14]; < 0.001 AD = 32.6%
Therapy discontinuation due to adverse events					
	1,363	317 (23.3)	1,385	18 (1.3)	17.9 [11.2; 28.6]; < 0.001 AD = 22.0%
Specific adverse events					
Skin and subcutaneous tissue disorders (SOC, AEs)	1,363	546 (40.1)	1,385	327 (23.6)	1.70 [1.51; 1.90]; < 0.001 AD = 16.5%
Vascular disorders (SOC, SAEs)	1,363	22 (1.6)	1,385	6 (0.4)	3.73 [1.52; 9.16]; 0.002 AD = 1.2%
Blood and lymphatic system disorders (SOC, severe AEs)	1,363	215 (15.8)	1,385	16 (1.2)	13.65 [8.26; 22.57]; < 0.001 AD = 14.6%
Neutropenia (PT, severe AEs)	1,363	143 (10.5)	1,385	4 (< 1)	36.33 [13.49; 97.84]; < 0.001 AD = 10.2%
Eye disorders (SOC, severe AEs)	1,363	15 (1.1)	1,385	6 (0.4)	2.54 [0.99; 6.53]; 0.047 AD = 0.7%
Gastrointestinal disorders (SOC, severe AEs)	1,363	159 (11.7)	1,385	21 (1.5)	7.69 [4.91; 12.05]; < 0.001 AD = 10.2%
Diarrhoea (PT, severe AEs)	1,363	133 (9.8)	1,385	2 (< 1)	67.57 [16.76; 272.46]; < 0.001 AD = 9.7%
General disorders and administration site conditions (SOC, severe AEs)	1,363	60 (4.4)	1,385	9 (0.6)	6.77 [3.38; 13.60]; < 0.001 AD = 3.8%

Infections and infestations (SOC, severe AEs)	1,363	77 (5.6)	1,385	39 (2.8)	2.01 [1.37; 2.93]; < 0.001 AD = 2.8%
Physical examinations (SOC, severe AEs)	1,363	256 (18.8)	1,385	33 (2.4)	7.88 [5.53; 11.24]; < 0.001 AD = 16.4%
Metabolism and nutrition disorders (SOC, severe AEs)	1,363	69 (5.1)	1,385	26 (1.9)	2.70 [1.73; 4.21]; < 0.001 AD = 3.2%
Musculoskeletal and connective tissue disorders (SOC, severe AEs)	1,363	17 (1.2)	1,385	38 (2.7)	0.45 [0.26; 0.80]; 0.005 AD = 1.5%
Renal and urinary disorders (SOC, severe AEs)	1,363	15 (1.1)	1,385	4 (0.3)	3.81 [1.27; 11.45]; 0.010 AD = 0.8%
Respiratory, thoracic and mediastinal disorders (SOC, severe AEs)	1,363	27 (2.0)	1,385	11 (0.8)	2.49 [1.24; 5.01]; 0.008 AD = 1.2%

[a] p value: log-rank test. No data on the model available; presumably an unstratified Cox proportional hazards model
[b] IQWiG's own calculation, unconditional exact test (CSZ method according to Martin Andrés et al.[2])
[c] Information on absolute difference (AD) only in case of statistically significant difference; own calculation
[d] MMRM with the variables: Value at the start of the study, treatment, visit, treatment*visit.
[e] Higher (increasing) values mean minor symptomatology; positive effects mean an advantage for the intervention (scale range 0 to 52).
[f] Higher (increasing) values mean better health status; positive effects mean an advantage for the intervention (scale range 0 to 100).
[g] Higher (increasing) values mean better health-related quality of life; positive effects mean an advantage for the intervention (scale range 0 to 148).

Abbreviations used:
AD = absolute difference; CTCAE = Common Terminology Criteria for Adverse Events; FACT-B = Functional Assessment of Cancer Therapy – Breast; FACIT-Fatigue = Functional Assessment of Chronic Illness Therapy – Fatigue; HR = hazard ratio; CI = confidence interval; MMRM = mixed model with repeated measures; MV = mean value; MD = mean difference; N = number of patients evaluated; n = number of patients with (at least one) event; n.c. = not calculable; n.r. = not reached; RR = relative risk; SD = standard deviation; SE = standard error; SMD = standardised mean difference; SOC = system organ class; VAS = visual analogue scale; vs = versus

"

4. In number 2 "**Number of patients or demarcation of patient groups eligible for treatment**", the information is amended as follows:

   a) After heading a1), the information "approx. 2,360 - 4,130 female patients" is replaced by the information "approximately 2,500 to 4,600 female patients".

[2] Martín Andrés A, Silva Mato A. Choosing the optimal unconditional test for comparing two independent proportions. Computat Stat Data Anal 1994; 17(5): 555-574. https://dx.doi.org/10.1016/0167-9473(94)90148-1.

b) After heading a2), the information "approx. 4,470 - 5,220 female patients" is replaced by the information "approximately 5,000 to 5,500 female patients".

5. In number 4 "**Treatment costs**", the information is amended as follows:

a) The information following the heading "a1) Premenopausal women with hormone receptor-positive, HER2-negative early breast cancer at high risk of recurrence" is replaced by the following information:

"

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Abemaciclib in combination with endocrine therapy	
1st to 2nd treatment year	
Abemaciclib	€ 24,868.93
Tamoxifen	€ 91.10
Anastrozole	€ 143.63
Letrozole	€ 170.12
Exemestane	€ 425.48
Total	€ 24,960.03 – € 25,294.41
LHRH agonist[3]	€ 1,906.92 – € 2,783.47
Appropriate comparator therapy:	
Tamoxifen (if applicable, with additional ovarian function suppression)	
1st to at least 5th treatment year	
Tamoxifen	€ 91.10
If applicable, LHRH agonist[3]	€ 1,906.92 – € 2,783.47
Total	€ 91.10 – € 2,874.57
Olaparib as monotherapy or in combination with endocrine therapy (only female patients with germline BRCA1/2-mutations are eligible)	
1st treatment year	
Olaparib as monotherapy	
Olaparib	€ 59,214.40
Olaparib in combination with endocrine therapy	
Olaparib	€ 59,214.40
Tamoxifen	€ 91.10
Anastrozole	€ 143.63
Letrozole	€ 170.12
Exemestane	€ 425.48
Total	€ 59,305.50 – € 59,639.88

[3] Goserelin, leuprorelin or triptorelin

Designation of the therapy	Annual treatment costs/ patient
LHRH agonist[3]	€ 1,906.92 – € 2,783.47
An aromatase inhibitor (anastrozole or letrozole or exemestane) in combination with ovarian function suppression (exemestane only in combination with triptorelin)	
1st to 5th treatment year	
Anastrozole	€ 143.63
LHRH agonist[3]	€ 1,906.92 – € 2,783.47
Total	€ 2,050.55 – € 2,927.10
1st to 5th treatment year	
Letrozole	€ 170.12
LHRH agonist[3]	€ 1,906.92 – € 2,783.47
Total	€ 2,077.04 – € 2,953.59
1st to 5th treatment year	
Exemestane	€ 425.48
Triptorelin	€ 2,684.50
Total	€ 3,109.98
Ribociclib in combination with an aromatase inhibitor	
1st to 3rd treatment year	
Ribociclib	€ 19,772.62
Anastrozole	€ 143.63
Letrozole	€ 170.12
Exemestane	€ 425.48
Total	€ 19,916.25 – € 20,198.10
LHRH agonist[3]	€ 1,906.92 – € 2,783.47

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 June 2026)

Costs for additionally required SHI services: not applicable

"

b) The information following the heading "a2) Postmenopausal women with hormone receptor-positive, HER2-negative early breast cancer at high risk of recurrence" is replaced by the following information:

"

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Abemaciclib in combination with endocrine therapy	
1st to 2nd treatment year	

Designation of the therapy	Annual treatment costs/ patient
Abemaciclib	€ 24,868.93
Tamoxifen	€ 91.10
Anastrozole	€ 143.63
Letrozole	€ 170.12
Exemestane	€ 425.48
Total	€ 24,960.03 – € 25,294.41
Appropriate comparator therapy:	
Aromatase inhibitor (anastrozole or letrozole) alone, or, if applicable, tamoxifen if aromatase inhibitors are unsuitable	
1st to 5th treatment year	
Anastrozole	€ 143.63
1st to 5th treatment year	
Letrozole	€ 170.12
1st to at least 5th treatment year	
Tamoxifen[4]	€ 91.10
Aromatase inhibitor (anastrozole or exemestane) in sequence after tamoxifen	
Anastrozole in sequence after tamoxifen	
Up to the 2nd or 3rd treatment year	
Tamoxifen	€ 91.10
From the 3rd or 4th up to the 5th treatment year	
Anastrozole	€ 143.63
Exemestane in sequence after tamoxifen	
Up to the 2nd or 3rd treatment year	
Tamoxifen	€ 91.10
From the 3rd or 4th up to the 5th treatment year	
Exemestane	€ 425.48
Olaparib as monotherapy or in combination with endocrine therapy (only female patients with germline BRCA1/2-mutations are eligible)	
1st treatment year	
Olaparib as monotherapy	
Olaparib	€ 59,214.40
Olaparib in combination with endocrine therapy	
Olaparib	€ 59,214.40
Tamoxifen	€ 91.10
Anastrozole	€ 143.63

[4] If aromatase inhibitors are unsuitable.

Designation of the therapy	Annual treatment costs/ patient
Letrozole	€ 170.12
Exemestane	€ 425.48
Total	€ 59,305.50 – € 59,639.88
Ribociclib in combination with an aromatase inhibitor	
1st to 3rd treatment year	
Ribociclib	€ 19,772.62
Anastrozole	€ 143.63
Letrozole	€ 170.12
Exemestane	€ 425.48
Total	€ 19,916.25 – € 20,198.10

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 15 June 2026)

Costs for additionally required SHI services: not applicable

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II. The resolution will enter into force on the day of its publication on the G-BA website on 20 August 2026.

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

Berlin, 20 August 2026

Federal Joint Committee
in accordance with Section 91 SGB V

The Chair

Dr Optendrenk