

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
Niraparib/ abiraterone acetate (new therapeutic indication:
metastatic hormone-sensitive prostate cancer, BRCA 1/2
mutations, in combination with prednis(ol)one and androgen
deprivation therapy)

From 3 September 2026

At their session on 3 September 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 following information shall be added after number 4 to the information on the benefit assessment of Niraparib/ abiraterone acetate in accordance with the resolution of 2 May 2024:**

Niraparib/ abiraterone acetate

Resolution of: 3 September 2026

Entry into force on: 3 September 2026

Federal Gazette, BAnz AT DD. MM YYYY Bx

New therapeutic indication (according to the marketing authorisation of 6 March 2026):

Akeega is indicated with prednisone or prednisolone:

- in combination with androgen deprivation therapy (ADT) for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations (germline and/or somatic).

Therapeutic indication of the resolution (resolution of 3 September 2026):

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 metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic)

Appropriate comparator therapy:

- conventional androgen deprivation in combination with apalutamide
or
- conventional androgen deprivation in combination with enzalutamide
or
- conventional androgen deprivation in combination with abiraterone acetate and prednisone or prednisolone (only for patients with newly diagnosed, high-risk prostate cancer)
or
- conventional androgen deprivation in combination with darolutamide and docetaxel

Extent and probability of the additional benefit of niraparib/ abiraterone acetate in combination with prednisone or prednisolone and an androgen deprivation therapy (ADT) versus abiraterone acetate in combination with prednisone and an ADT:

- a) Adult patients with newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic) and a high-risk profile

An additional benefit is not proven.

- b) Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations who are not newly diagnosed and/or do not have a high-risk profile

An additional benefit is not proven.

Study results according to endpoints:¹

- a) Adult patients with newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic) and a high-risk profile

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 the "symptomatic progression" endpoint.
Health-related quality of life	↔	No relevant differences for the benefit assessment.
Side effects	↓↓	Disadvantages in the endpoints of severe AEs and SAEs.
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		

¹ Data from the dossier assessment of the IQWiG (A26-31) and from the addendum (A26-98), unless otherwise indicated.

AMPLITUDE study:

- Ongoing, randomised, controlled, double-blind phase III study
- Relevant patient population:
Patients with newly diagnosed high-risk mHSPC and BRCA 1/2 mutations
- Niraparib/ abiraterone acetate + placebo + prednisone + ADT
versus placebo + abiraterone acetate + prednisone + ADT

Mortality

Endpoint	Niraparib/ abiraterone acetate + placebo + prednisone + ADT		Placebo + abiraterone acetate + prednisone + ADT		Intervention vs control
	N	Median time in months [95% CI] <i>Patients with event n (%)</i>	N	Median time in months [95% CI] <i>Patients with event n (%)</i>	Hazard ratio [95% CI] p value ^a Absolute difference (AD) ^b
Overall survival					
	58	n.r. [32.13; n.c.] 23 (39.7)	50	36.04 [27.89; n.c.] 28 (56.0)	0.77 [0.44; 1.33] 0.344

Morbidity

Endpoint	Niraparib/ abiraterone acetate + placebo + prednisone + ADT		Placebo + abiraterone acetate + prednisone + ADT		Intervention vs control
	N	Median time in months [95% CI] <i>Patients with event n (%)</i>	N	Median time in months [95% CI] <i>Patients with event n (%)</i>	Hazard ratio [95% CI] p value ^a Absolute difference (AD) ^b
Symptomatic progression					
Symptomatic progression excluding the subcomponent of death from any cause ^c	58	n.r. - 8 (13.8)	50	n.c. [39.72; n.c.] 18 (36.0)	0.33 [0.14; 0.79] 0.013
Incidence of cancer-related morbidity events ^d	58	- 1 (1.7)	50	- 4 (8.0)	-

External radiotherapy for skeletal or pelvic symptoms ^e	58	- 4 (6.9)	50	- 7 (14.0)	-
Tumour-related orthopaedic surgical intervention ^f	58	- 0 (0)	50	- 0 (0)	-
The start of a new systematic cancer treatment due to cancer symptoms ^g	58	- 3 (5.2)	50	- 4 (8.0)	-
Performance of other cancer-related procedures ^h	58	- 0 (0)	50	- 3 (6.0)	-
Symptomatic progression, taking into account death from any cause as a competing event ⁱ (presented additionally)	58	Events, n (%): 8 (13.8) Competing events, n (%): 16 (27.6)	50	Events, n (%): 18 (36.0) Competing events, n (%): 12 (24.0)	0.30 [0.13; 0.72] 0.007 Gray test p value: 0.008
Worst pain (BPI-SF item 3)^j					
	58	18.83 [11.96; n.c.] 30 (51.7)	50	21.16 [10.12; 40.54] 27 (54.0)	0.96 [0.56; 1.63] 0.872
Pain intensity (BPI SF items 3-6) (presented additionally)^j					
	58	19.45 [14.52; n.c.] 28 (48.3)	50	21.16 [11.01; n.c.] 25 (50.0)	0.95 [0.55; 1.64] 0.850
Impairment due to pain (BPI-SF item 9a-g)^j					
	58	33.22 [15.67; n.c.] 24 (41.4)	50	22.01 [10.12; n.c.] 26 (52.0)	0.83 [0.47; 1.45] 0.506

Health status (EQ-5D VAS) ^k					
	58	16.62 [6.47; 37.78] 31 (53.4)	50	24.38 [14.88; n.c.] 25 (50.0)	1.26 [0.73; 2.16] 0.400

Health-related quality of life

Endpoint	Niraparib/ abiraterone acetate + placebo + prednisone + ADT		Placebo + abiraterone acetate + prednisone + ADT		Intervention vs control
	N	Median time in months [95% CI] <i>Patients with event n (%)</i>	N	Median time in months [95% CI] <i>Patients with event n (%)</i>	Hazard ratio [95% CI] p value ^a Absolute difference (AD) ^b
FACT-P					
Total score ^l	58	n.r. [16.62; n.c.] 19 (32.8)	50	22.11 [11.60; n.c.] 24 (48.0)	0.65 [0.35; 1.22] 0.177
Physical well-being ^m	58	17.45 [6.47; n.c.] 31 (53.4)	50	44.22 [11.04; n.c.] 24 (48.0)	1.33 [0.78; 2.29] -
Social/ family well-being ^m	58	17.74 [8.35; 40.38] 31 (53.4)	50	11.04 [7.46; 25.82] 30 (60.0)	0.82 [0.49; 1.38] -
Emotional well-being ⁿ	58	14.98 [7.42; 29.80] 32 (55.2)	50	17.51 [6.47; n.c.] 25 (50.0)	1.12 [0.65; 1.93] -
Functional well-being ^m	58	9.23 [3.65; 15.67] 37 (63.8)	50	11.04 [4.57; 36.96] 30 (60.0)	1.18 [0.72; 1.94] -
Prostate cancer-specific subscale ^o	58	n.r. [10.25; n.c.] 24 (41.4)	50	n.r. [14.88; n.c.] 22 (44.0)	1.11 [0.62; 2.00] -

Side effects

Endpoint	Niraparib/ abiraterone acetate + placebo + prednisone + ADT		Placebo + abiraterone acetate + prednisone + ADT		Intervention vs control
	N	Median time in months [95% CI] <i>Patients with event n (%)</i>	N	Median time in months [95% CI] <i>Patients with event n (%)</i>	Hazard ratio [95% CI] p value ^a Absolute difference (AD) ^a
Total adverse events (presented additionally)					
	58	0.46 [0.20; 0.53] 58 (100.0)	50	0.69 [0.39; 1.28] 49 (98.0)	-
Serious adverse events (SAEs)					
	58	32.07 [14.46; n.c.] 29 (50.0)	50	n.r. [29.34; n.c.] 12 (24.0)	2.10 [1.07; 4.13] 0.028
Severe adverse events (CTCAE grade 3 or 4)					
	58	2.79 [1.87; 4.80] 51 (87.9)	50	21.12 [9.49; n.c.] 23 (46.0)	3.86 [2.31; 6.46] < 0.001 AD: 18.3 months
Therapy discontinuation due to adverse events ^p					
	58	n.r. - 13 (22.4)	50	n.r. - 4 (8.0)	2.51 [0.81; 7.75] 0.099
PRO-CTCAE					
	No suitable data ^q				
Specific adverse events ^r					
MDS (AEs)	n.d. ^s				
AML (AEs)	n.d. ^s				
Anaemia (PT, severe AEs ^t)	58	n.r. - 19 (32.8)	50	n.r. - 2 (4.0)	9.96 [2.30; 43.04] < 0.001
Hypertension (PT, severe AEs ^t)	58	n.r. [7.39; n.c.] 23 (39.7)	50	n.r. - 5 (10.0)	4.62 [1.74; 12.22] 0.001
^a . HR and 95% CI from a stratified Cox proportional hazards model; p value from a stratified log-rank test; each stratified by tumour volume (high vs low); for the "symptomatic progression" endpoint: p value: calculated using a stratified Cox proportional hazards model					
^b . Absolute difference (AD) given only in the case of a statistically significant difference; own calculation					
^c . Operationalisation with the date of occurrence of the symptom (AE date), excluding grade 1 pathological fracture; consists of the subcomponents: occurrence of cancer-related morbidity events, external					

radiotherapy for skeletal or pelvic symptoms, tumour-related orthopaedic surgical intervention, initiation of new systemic cancer therapy due to cancer symptoms, and performance of other cancer-related procedures

- d. Number of patients with an event in the subcomponent of occurrence of cancer-related morbidity events: 1 vs 5
- e. Number of patients with an event in the subcomponent of external radiotherapy for skeletal or pelvic symptoms: 4 vs 8
- f. Number of patients with an event in the subcomponent of tumour-related orthopaedic surgical intervention: 0 vs 0
- g. Number of patients with an event in the subcomponent of initiation of new systemic cancer therapy due to cancer symptoms: 3 vs 6
- h. Number of patients with an event in the subcomponent of performance of other cancer-related procedures: 0 vs 3
- i. Additional analysis using a stratified Fine-Gray model, taking into account death from any cause without prior symptomatic progression as competing events
- j. Time to first deterioration. An increase by ≥ 1.5 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–10).
- k. Time to first deterioration. A decrease by ≥ 15 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–100).
- l. Time to first deterioration. A decrease by ≥ 23.4 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–156).
- m. Time to first deterioration. A decrease by ≥ 4.2 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–28).
- n. Time to first deterioration. A decrease by ≥ 3.6 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–24).
- o. Time to first deterioration. A decrease by ≥ 7.2 points compared to the start of the study is considered a clinically relevant deterioration (scale range 0–48).
- p. ≥ 1 active ingredient component
- q. The PRO-CTCAE questionnaire was collected exclusively at study sites in the USA (in English) and was therefore not submitted by the pharmaceutical company for the relevant sub-population.
- r. Selection according to the methodology of the IQWiG; selection using events occurred in the study, based on frequency and differences between treatment arms, and taking into account patient relevance.
- s. No data available on the relevant sub-population; according to the information in Module 5, 1 MDS/AML event was observed in patients with BRCA 1/2 mutations in the intervention arm
- t. Operationalised as CTCAE grade ≥ 3

Abbreviations used:

AD = absolute difference; ADT = androgen deprivation therapy; AML = acute myeloid leukaemia; BPI-SF = Brief Pain Inventory – Short Form; BRCA = breast cancer susceptibility gene; CTCAE = Common Terminology Criteria for Adverse Events; FACT-P = Functional Assessment of Cancer Therapy-Prostate; HR = hazard ratio; n.d. = no data available; CI = confidence interval; MDS = myelodysplastic syndrome; mHSPC = metastatic hormone-sensitive prostate cancer; n = number of patients with (at least 1) event; N = number of patients evaluated; n.c. = not calculable; n.r. = not reached; PRO-CTCAE = Patient-reported Outcomes version of the CTCAE; PT = preferred term; RCT = randomised controlled trial; SAE = serious adverse event; AE = adverse event; VAS = visual analogue scale

- b) Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) and BRCA 1/2 mutations who are not newly diagnosed and/or do not have a high-risk profile

Summary of results for relevant clinical endpoints

Endpoint category	Direction of effect/ risk of bias	Summary
Mortality	∅	No data available.
Morbidity	∅	No data available.
Health-related quality of life	∅	No data available.
Side effects	∅	No data available.
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		

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

Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic)

Approximately 330 to 470 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 Akeega (active ingredient: niraparib/ abiraterone acetate) at the following publicly accessible link (last access: 25 August 2026):

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

Treatment with niraparib/ abiraterone acetate should only be initiated and monitored by specialists in internal medicine, haematology, oncology and urology who are experienced in the treatment of patients with prostate cancer, and other doctors from other specialist groups participating in the Oncology Agreement. Medicinal castration with a GnRH agonist or antagonist should be continued during the treatment of patients who have not been surgically castrated.

4. Treatment costs

Annual treatment costs:

The costs for the first year of treatment are shown for the cost representation in the resolution.

Adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) with BRCA 1/2 mutations (germline and/or somatic)

Designation of the therapy	Annual treatment costs/ patient
Medicinal product to be assessed:	
Niraparib/ abiraterone acetate in combination with prednisone or prednisolone and androgen deprivation therapy (ADT)	
Niraparib/ abiraterone acetate	€ 59,904.32
GnRH agonist/ GnRH antagonist Orchiectomy	€ 1,285.70 – € 2,451.26 € 4,809.90
Prednisone or prednisolone	€ 51.50 – € 55.92
Total	€ 61,241.52 – € 64,770.14

Appropriate comparator therapy:	
Conventional androgen deprivation in combination with apalutamide	
GnRH agonist/ GnRH antagonist Orchiectomy	€ 1,285.70 – € 2,451.26 € 4,809.90
Apalutamide	€ 34,975.73
Total	€ 36,261.43 – € 39,785.63
Conventional androgen deprivation in combination with enzalutamide	
GnRH agonist/ GnRH antagonist Orchiectomy	€ 1,285.70 – € 2,451.26 € 4,809.90
Enzalutamide	€ 40,700.24
Total	€ 41,985.94 – € 45,510.14
Conventional androgen deprivation in combination with abiraterone acetate and prednisone or prednisolone	
GnRH agonist/ GnRH antagonist Orchiectomy	€ 1,285.70 – € 2,451.26 € 4,809.90
Abiraterone acetate	€ 1,632.46
Prednisone or prednisolone	€ 51.50 – € 55.92
Total	€ 2,969.66 – € 6,498.28
Conventional androgen deprivation in combination with darolutamide and docetaxel	
GnRH agonist/ GnRH antagonist Orchiectomy	€ 1,285.70 – € 2,451.26 € 4,809.90

Darolutamide	€ 45,955.98
Docetaxel	€ 2,945.10
If applicable, prednisone or prednisolone	€ 42.33 – € 45.96
Total	€ 50,229.11 – € 53,756.94

Costs after deduction of statutory rebates (LAUER-TAXE® as last revised: 1 July 2026)

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
Appropriate comparator therapy					
Conventional androgen deprivation in combination with darolutamide and docetaxel					
Docetaxel	Surcharge for the preparation of a parenteral solution containing cytostatic agents	€ 100	1	6	€ 600

II. The resolution will enter into force on the day of its publication on the G-BA website on 3 September 2026.

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

Berlin, 3 September 2026

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

Dr Optendrenk