Drug assessment at a glance: A26-31[1]

Niraparib/abiraterone acetate (prostate cancer)

21 September 2026

[1] This is a courtesy translation of the summary provided as a service by IQWiG. For further information on the subject matter and the result of the assessment, please refer to the dossier assessment for Project A26-31. The GBA decides on the added benefit.

Research question for the benefit assessment

Population	Adults with mHSPC and BRCA1/2 mutations (germline and/or somatic)
Intervention	niraparib/abiraterone acetate + prednisone or prednisolone + androgen deprivation therapy
Comparator	▪ Conventional androgen deprivation therapy in combination with apalutamide or ▪ Conventional androgen deprivation therapy in combination with enzalutamide or ▪ Conventional androgen deprivation therapy in combination with abiraterone acetate and prednisone or prednisolone (only for patients with newly diagnosed high-risk prostate cancer) or ▪ Conventional androgen deprivation therapy in combination with darolutamide and docetaxel
Outcomes	At least one patient-relevant outcome

Overview of positive and negative effects

	Size of the effects	Informative value of the effects
Mortality	↔	–
Morbidity	↔ (symptomatic progression)	–
Symptoms	↔	–
Health-related quality of life	↔	–
Side effects	↓↓↓	★
	ø No (suitable) data ↔ No advantage or disadvantage ↑ / ↓ Small advantage/disadvantage ↑↑ / ↓↓ Moderate advantage/disadvantage ↑↑↑ / ↓↓↓ Large advantage/disadvantage	– Not applicable ★ Low ★★ Moderate ★★★ High

Overall: No advantage or disadvantage

Evidence base and noteworthy aspects

- Evidence base: the double-blind RCT AMPLITUDE comparing niraparib/abiraterone acetate + placebo + prednisone + androgen deprivation therapy versus placebo + abiraterone acetate + prednisone + androgen deprivation therapy

- Symptomatic progression outcome: The predominance of the ‘death from any cause’ subcomponent meant that, given the available data, the results could only be interpreted to a limited extent in relation to the construct of the composite outcome of symptomatic progression.

Key study findings

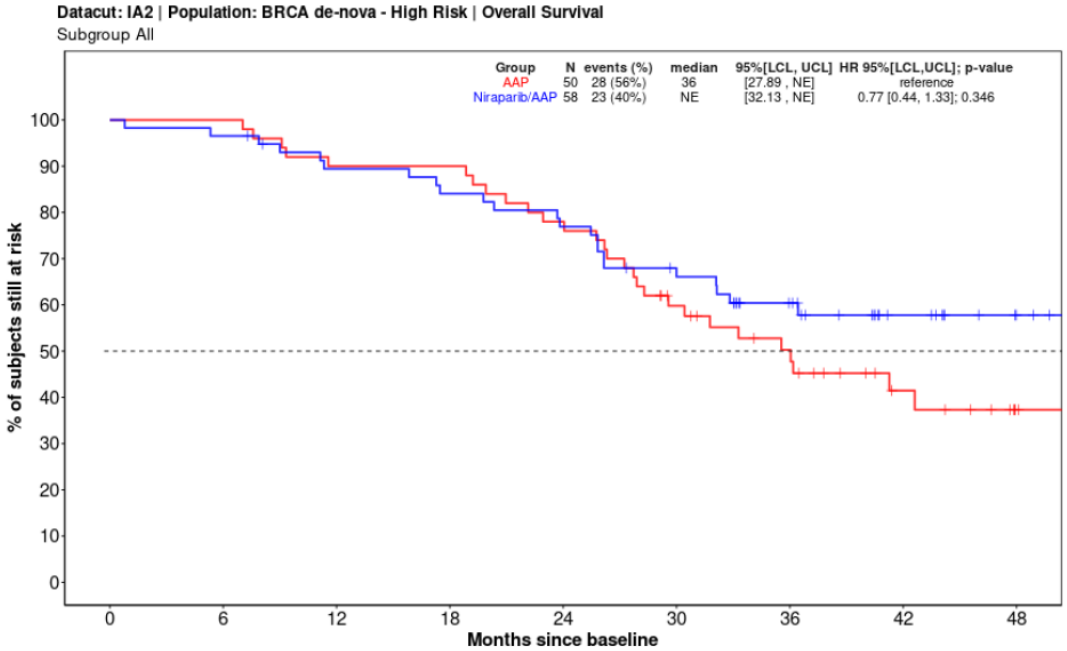
Study Outcome category Outcome	niraparib/abiraterone acetate + placebo + prednisone + ADT		placebo + abiraterone acetate + prednisone + ADT		niraparib/abiraterone acetate + placebo + prednisone + ADT vs. placebo + abiraterone acetate + prednisone + ADT
	N	Median time to event in months [95% CI] Patients with event n (%)	N	Median time to event in months [95% CI] Patients with event n (%)	HR [95% CI]; p-value
AMPLITUDE					
Mortality					
Overall survival	58	NA [32.13; NC] 23 (39.7)	50	36.04 [27.89; NC] 28 (56.0)	0.77 [0.44; 1.33]; 0.344
Morbidity					
Symptomatic progression, including the subcomponent 'death from any cause'	58	NA [28.12; NC] 24 (41.4)	50	35.5 [25.69; 42.61] 30 (60.0)	0.67 [0.39; 1.15]; 0.143
Occurrence of cancer-related morbid events	58	– 1 (1.7)	50	– 4 (8.0)	–
Radiotherapy for skeletal or pelvic symptoms	58	– 4 (6.9)	50	– 7 (14.0)	–
Tumour-related orthopaedic-surgical intervention	58	– 0 (0)	50	– 0 (0)	–

Study Outcome category Outcome	niraparib/abiraterone acetate + placebo + prednisone + ADT		placebo + abiraterone acetate + prednisone + ADT		niraparib/abiraterone acetate + placebo + prednisone + ADT vs. placebo + abiraterone acetate + prednisone + ADT
	N	Median time to event in months [95% CI] Patients with event n (%)	N	Median time to event in months [95% CI] Patients with event n (%)	HR [95% CI]; p-value
Initiation of a new systemic anti-cancer therapy because of cancer symptoms	58	– 3 (5.2)	50	– 4 (8.0)	–
Use of other cancer-related procedures	58	– 0 (0)	50	– 3 (6.0)	–
Death from any cause	58	– 16 (27.6)	50	– 12 (24.0)	–
Worst pain (BPI-SF Item 3)	58	18.83 [11.96; NC] 30 (51.7)	50	21.16 [10.12; 40.54] 27 (54.0)	0.96 [0.56; 1.63]; 0.872
Pain interference (BPI-SF Item 9a-g)	58	33.22 [15.67; NC] 24 (41.4)	50	22.01 [10.12; NC] 26 (52.0)	0.83 [0.47; 1.45]; 0.506
Health status (EQ-5D VAS)	58	16.62 [6.47; 37.78] 31 (53.4)	50	24.38 [14.88; NC] 25 (50.0)	1.26 [0.73; 2.16]; 0.400

Study Outcome category Outcome	niraparib/abiraterone acetate + placebo + prednisone + ADT		placebo + abiraterone acetate + prednisone + ADT		niraparib/abiraterone acetate + placebo + prednisone + ADT vs. placebo + abiraterone acetate + prednisone + ADT
	N	Median time to event in months [95% CI] Patients with event n (%)	N	Median time to event in months [95% CI] Patients with event n (%)	HR [95% CI]; p-value
Health-related quality of life					
FACT-P					
Total score	58	NA [16.62; NC] 19 (32.8)	50	22.11 [11.60; NC] 24 (48.0)	0.65 [0.35; 1.22]; 0.177
Physical wellbeing	58	17.45 [6.47; NC] 31 (53.4)	50	44.22 [11.04; NC] 24 (48.0)	1.33 [0.78; 2.29]
Social/family wellbeing	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 wellbeing	58	14.98 [7.42; 29.80] 32 (55.2)	50	17.51 [6.47; NC] 25 (50.0)	1.12 [0.65; 1.93]
Functional wellbeing	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	58	NA [10.25; NC] 24 (41.4)	50	NA [14.88; NC] 22 (44.0)	1.11 [0.62; 2.00]

Study Outcome category Outcome	niraparib/abiraterone acetate + placebo + prednisone + ADT		placebo + abiraterone acetate + prednisone + ADT		niraparib/abiraterone acetate + placebo + prednisone + ADT vs. placebo + abiraterone acetate + prednisone + ADT
	N	Median time to event in months [95% CI] Patients with event n (%)	N	Median time to event in months [95% CI] Patients with event n (%)	HR [95% CI]; p-value
Side effects					
AEs (supplementary information)	58	0.46 [0.20; 0.53] 58 (100.0)	50	0.69 [0.39; 1.28] 49 (98.0)	–
SAEs	58	32.07 [14.46; NC] 29 (50.0)	50	NA [29.34; NC] 12 (24.0)	2.10 [1.07; 4.13]; 0.028
Severe AEs	58	2.79 [1.87; 4.80] 51 (87.9)	50	21.12 [9.49; NC] 23 (46.0)	3.86 [2.31; 6.46]; <0.001
Discontinuation due to AEs (≥1 drug component)	58	NA 13 (22.4)	50	NA 4 (8.0)	2.51 [0.81; 7.75]; 0.099

Kaplan-Meier curves on overall survival



Number at risk									
AAP	50	50	45	45	39	27	20	10	2
Niraparib/AAP	58	56	50	47	43	35	25	12	4
Number (%) censored									
AAP	0(0%)	0(0%)	0(0%)	0(0%)	0(0%)	3(6%)	6(12%)	13(26%)	20(40%)
Niraparib/AAP	0(0%)	0(0%)	2(3%)	2(3%)	2(3%)	4(7%)	11(19%)	23(40%)	32(55%)

References

Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen. Niraparib/Abirateronacetat (Prostatakarzinom); Nutzenbewertung gemäß § 35a SGB V; Dossierbewertung [online]. 2026 [Accessed: 03.09.2026]. URL: https://doi.org/10.60584/A26-31_V1.1.

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English translations for this project are published at https://www.iqwig.de/en/projects/a26-31.html and https://www.iqwig.de/en/projects/a26-98.html.

Publisher details

Publisher

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