Healthcare Resource Utilization and Medical Costs in Patients With Metastatic Castration Sensitive Prostate Cancer Initiating Apalutamide or Darolutamide in the United States

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Key Takeaways

In this descriptive study of patients with mCSPC initiating APA or DARO, post-index annual medical HRU and costs varied across cohorts, with the highest values observed among those initiating DARO+C, followed by DARO-NC and then APA

Variations in demographics and clinical characteristics, including insurance type, concurrent ADT use, and sites of metastasis, were also observed across cohorts, APA and DARO-NC patients showing greater similarity than DARO+C patients

Conclusions

Post-index PPPY medical HRU and costs were numerically higher among patients initiating DARO (with or without concurrent chemotherapy) relative to those initiating APA

Further adjusted analyses in balanced cohorts are warranted to better assess HRU and costs in patients with mCSPC initiating ARPIs

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Disclosures
RW, SB, and CC are employees and stockholders of Johnson & Johnson. KJ was an employee at the time the study was performed.

Introduction

- Several androgen receptor pathway inhibitors (ARPIs) have been approved, in combination with androgen deprivation therapy (ADT), for the treatment of metastatic castration sensitive prostate cancer (mCSPC), also known as metastatic hormone-sensitive prostate cancer (mHSPC)[1,2]
- Real-world studies have reported that patients treated with apalutamide (APA) experienced better clinical outcomes and lower medical costs than those treated with other ARPIs such as enzalutamide and abiraterone acetate[3,4]
- Darolutamide (DARO) is a more recently approved ARPI for mCSPC[2]
- However, real-world data describing healthcare resource utilization (HRU) and medical costs among patients treated with DARO is limited

Objective

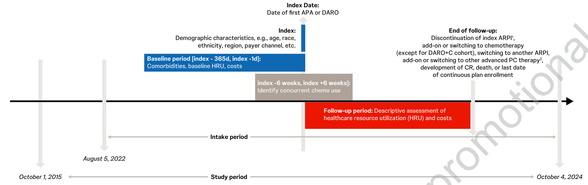
- To describe HRU and medical costs among patients with mCSPC treated with APA or DARO

Methods

Study design and data source

- A retrospective, descriptive analysis was conducted using healthcare claims from the Komodo Research Dataset (data cutoff date, October 4, 2024; **Figure 1**)

Figure 1: Study design



[1]Defined as having a treatment gap of >90 days in index ARPI
[2]PARP inhibitors, radiopharmaceuticals, and immunotherapy
Abbreviations: APA, apalutamide; ARPI, androgen receptor pathway inhibitor; CR, castration resistance; DARO, darolutamide; DARO+C: darolutamide with concurrent chemotherapy; HRU, healthcare resource utilization; mCSPC, metastatic castration sensitive prostate cancer; PARP, poly ADP-ribose polymerase; PC, prostate cancer.

Study population

- ARPI-naïve patients with mCSPC who initiated APA or DARO on or after August 5, 2022, and had ≥12 months of pre-index continuous plan enrollment (the baseline period)
- The index date was defined as the date of the first paid pharmacy claim for APA or DARO
- Patients initiating DARO were stratified by receipt of concurrent chemotherapy (DARO+C; defined as receiving chemotherapy ≤6 weeks before and up to 6 weeks after the index date) or not (DARO-NC; no chemotherapy use ≤6 weeks before and up to 6 weeks after the index date)
- Patients were followed from the index date until the earliest of discontinuation of index ARPI (i.e., treatment gap >90 days), add-on or switching to chemotherapy (except for the DARO+C cohort), switching to another ARPI, add-on or switching to another advanced PC treatment, progression to castration resistance, death, end of continuous plan enrollment, or end of data availability (the follow-up period)

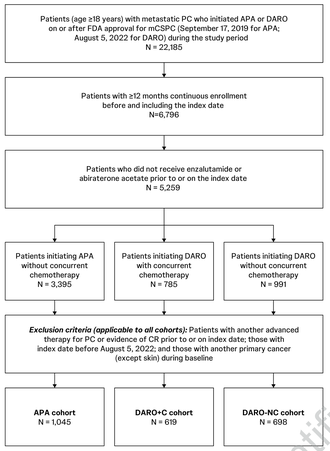
Data analysis

- All-cause and PC-related HRU and medical costs per-patient-per-year (PPPY) were reported during the baseline and follow-up periods
- PC-related HRU and costs were defined based on encounters with an ICD-10-CM diagnosis code C61 at any diagnosis position, or a claim with a procedure code for luteinizing hormone-releasing hormone, bilateral orchiectomy, or other National Comprehensive Cancer Network-recommended therapies for mCSPC
- Costs were inflation adjusted to 2024 US dollars and reported from the payer perspective
- All variables were descriptively summarized

Results

- Among eligible patients with mCSPC, 1,045 initiated APA and 1,317 initiated DARO. Of those receiving DARO, 619 (47.0%) received it with chemotherapy and 698 (53.0%) received it without chemotherapy (**Figure 2**)

Figure 2: Patient attrition



Abbreviations: APA, apalutamide; DARO, darolutamide; DARO+C, darolutamide with concurrent chemotherapy; DARO-NC, darolutamide without concurrent chemotherapy; mCSPC, metastatic castration sensitive prostate cancer; PC, prostate cancer; CR, castration resistance.

Patient characteristics

- Patient demographics and PC-related clinical characteristics are presented in **Table 1**
- The mean (SD) age at diagnosis was 71.9 (9.8) years for the APA cohort, 63.8 (7.9) years for the DARO+C cohort, and 68.5 (9.9) years for DARO-NC cohort
- Most patients in the APA cohort had Medicare insurance (61.6%), whereas the majority in the DARO+C cohort were commercially insured (59.9%). In the DARO-NC cohort, about half had Medicare (48.6%) and 42.3% had commercial insurance
- Across cohorts, most patients had de novo mCSPC on the index date (66.4% APA; 90.0% DARO+C; 75.1% DARO-NC) and received concurrent ADT (87.7% APA; 96.9% DARO+C; 84.7% DARO-NC)
- The most common site of metastasis was bone (71.1% APA; 87.6% DARO+C; 79.1% DARO-NC). Visceral involvement was observed in 9.4% of APA, 16.5% of DARO+C, and 13.5% of DARO-NC patients

Table 1: Patient demographics and clinical characteristics

Demographics	APA N=1,045	DARO+C N=619	DARO-NC N=698
Age, mean (SD), years	71.9 (9.8)	63.8 (7.9)	68.5 (9.9)
Sex, male, n (%)	1,018 (97.4)	611 (98.7)	681 (97.6)
Race and ethnicity, n (%)			
White	580 (55.5)	307 (49.6)	380 (54.4)
Black	185 (17.7)	88 (14.2)	130 (18.6)
Asian	27 (2.6)	13 (2.1)	11 (1.6)
Other or unknown	253 (24.2)	211 (34.1)	177 (25.4)
Geographic region, n (%)			
Northeast	203 (19.4)	152 (24.6)	271 (38.8)
Midwest	201 (19.2)	189 (30.5)	128 (18.3)
South	453 (43.3)	200 (32.3)	204 (29.2)
West	182 (17.4)	76 (12.3)	95 (13.6)
Unknown	<11	<11	<11
Payer type, n (%)			
Commercial	341 (32.6)	371 (59.9)	295 (42.3)
Medicare	644 (61.6)	181 (29.2)	339 (48.6)
Medicaid	59 (5.6)	67 (10.8)	60 (8.6)
Unknown	<11	<11	<11
Clinical characteristics			
Year of index ARPI initiation (%)			
2022	185 (17.7)	137 (22.1)	131 (18.8)
2023	554 (53.0)	351 (56.7)	352 (50.4)
2024	306 (29.3)	131 (21.2)	215 (30.8)
Time from the initial metastasis diagnosis to index date, median (IQR), months	2.6 (0.9–13.5)	1.2 (0.6–2.2)	1.8 (0.7–8.8)
Time from ADT initiation to index date, median (IQR), months	1.6 (0.1–12.2)	0.4 (0.0–1.4)	0.9 (0.0–6.4)
Metastasis site, n (%)			
Bone	743 (71.1)	542 (87.6)	552 (79.1)
Nodal	480 (45.9)	286 (46.2)	325 (46.6)
Visceral	98 (9.4)	102 (16.5)	94 (13.5)
Multiple sites, ≥2 sites out of 3	280 (26.8)	271 (43.8)	258 (37.0)
Quan-CCI score (excluding PC diagnosis), mean (SD)	7.0 (2.3)	7.2 (1.6)	7.1 (2.3)
Number of Quan-CCI comorbidities, mean (SD)	2.6 (1.7)	2.3 (1.5)	2.7 (1.8)
De novo mCSPC, n (%)	694 (66.4)	557 (90.0)	524 (75.1)
Concurrent use of ADT* n (%)	916 (87.7)	600 (96.9)	591 (84.7)

Note: Cells with counts ≤10 are represented as <11 in accordance with FDA's policy.
*defined as ADT use within 6 months before or after the index date.
Abbreviations: ADT, androgen deprivation therapy; APA, apalutamide cohort; ARPI, androgen receptor pathway inhibitor; DARO+C, darolutamide with concurrent chemotherapy cohort; DARO-NC, darolutamide without concurrent chemotherapy cohort; IQR, interquartile range; Quan-CCI, Quan-Charlson Comorbidity Index; mCSPC, metastatic castration sensitive prostate cancer; SD, standard deviation.

HRU

- The mean follow-up was 5.4 months for the APA cohort, 6.7 months for the DARO+C cohort, and 5.0 months for the DARO-NC cohort (**Table 2**)
- During the follow-up period, PC-related inpatient admissions occurred in 6.6% of APA patients, 14.1% of DARO+C patients, and 9.5% of DARO-NC patients
- The mean length of stay for PC-related acute inpatient admissions was 10.2 days PPPY for APA patients, 15.5 for DARO+C patients, and 17.9 for DARO-NC patients

Table 2: All-cause and PC-related healthcare resource utilization

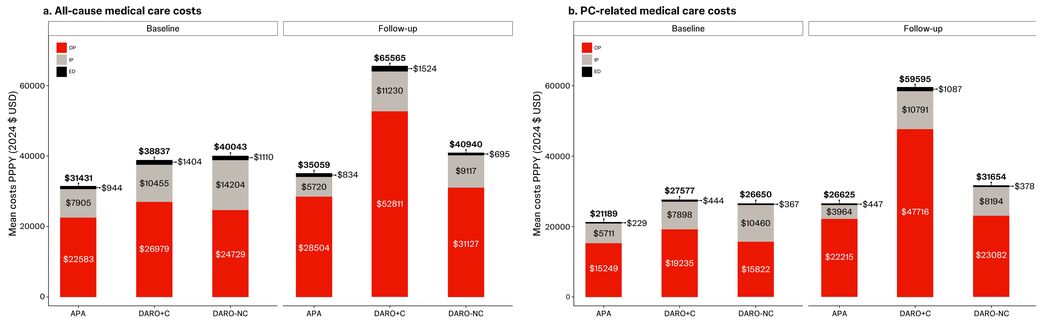
	Baseline			Follow-up		
	APA (n=1,045)	DARO+C (n=619)	DARO-NC (n=698)	APA (n=1,045)	DARO+C (n=619)	DARO-NC (n=698)
Patient follow-up duration, mean (SD), months	12 (0)	12 (0)	12 (0)	5.4 (5.1)	6.7 (5.5)	5.0 (4.8)
All-cause HRU						
Had ≥1 inpatient admissions, n (%)	239 (22.9)	160 (25.8)	203 (29.1)	87 (8.3)	89 (14.4)	77 (11.0)
Inpatient admissions, PPPY, mean (SD)	0.34 (0.81)	0.34 (0.68)	0.50 (1.16)	0.35 (1.91)	0.4 (1.29)	0.45 (1.79)
LOS of acute inpatient admissions in days, PPPY, mean (SD)	9.0 (14.2)	7.6 (7.4)	12.8 (31.5)	9.5 (15.7)	15.3 (35.3)	15.4 (29.4)
Had ≥1 ED visits, n (%)	336 (32.2)	248 (40.1)	259 (37.1)	153 (14.6)	134 (21.7)	84 (12.0)
Days with ED visits, PPPY, mean (SD)	0.61 (1.29)	0.82 (1.54)	0.71 (1.34)	0.5 (1.6)	0.73 (2.43)	0.44 (1.59)
Had ≥1 outpatient visits, n (%)	1043 (99.8)	617 (99.7)	697 (99.9)	947 (90.6)	603 (97.4)	651 (93.3)
Days with outpatient visits, PPPY, mean (SD)	29.6 (24.1)	27.2 (28.4)	30.9 (29.3)	39.3 (38.6)	44.6 (28.2)	39.1 (34.3)
PC-related HRU						
Had ≥1 PC-related inpatient admissions, n (%)	170 (16.3)	129 (20.8)	156 (22.3)	69 (6.6)	87 (14.1)	66 (9.5)
PC-related inpatient admissions, PPPY, mean (SD)	0.22 (0.59)	0.25 (0.58)	0.34 (0.91)	0.23 (1.27)	0.38 (1.23)	0.38 (1.67)
LOS of PC-related acute inpatient admissions in days, PPPY, mean (SD)	9.3 (14.7)	7.7 (7.9)	13.0 (32.6)	10.2 (15.9)	15.5 (35.6)	17.9 (32.4)
Had ≥1 PC-related ED visits, n (%)	81 (7.8)	70 (11.3)	72 (10.3)	77 (7.4)	91 (14.7)	41 (5.9)
Days with PC-related ED visits, PPPY, mean (SD)	0.11 (0.43)	0.16 (0.60)	0.13 (0.45)	0.2 (0.93)	0.36 (1.07)	0.18 (0.96)
Had ≥1 PC-related outpatient visits, n (%)	1030 (98.6)	612 (98.9)	688 (98.6)	894 (85.6)	599 (96.8)	619 (88.7)
Days with PC-related outpatient visits, PPPY, mean (SD)	11.8 (11.8)	10.2 (8.4)	11.3 (12.9)	22.5 (24.5)	31.9 (18.7)	23.0 (21.3)

Abbreviations: APA, apalutamide cohort; ARPI, androgen receptor pathway inhibitor; DARO+C, darolutamide with concurrent chemotherapy cohort; DARO-NC, darolutamide without concurrent chemotherapy cohort; ED, emergency department; HRU, healthcare resource utilization; LOS, length of stay; mCSPC, metastatic castration sensitive prostate cancer; PC, prostate cancer; PPPY, per patient per year; SD, standard deviation.

Costs

- During the follow-up period:
  - Mean all-cause medical cost PPPY was $35,059 for APA patients, $65,565 for DARO+C patients, and $40,940 for DARO-NC patients (**Figure 3**)
  - Mean PC-related medical cost PPPY was $26,625, $59,595, and $31,654, respectively (**Figure 3**)

Figure 3: All-cause and PC-related medical costs (PPPY) among patients with mCSPC treated with apalutamide or darolutamide



Note: The individual numbers may not sum to the total due to rounding adjustments.
Abbreviations: APA, apalutamide cohort; DARO+C, darolutamide with concurrent chemotherapy cohort; DARO-NC, darolutamide without concurrent chemotherapy cohort; ED, emergency department; mCSPC, metastatic castration sensitive prostate cancer; OP, outpatient; PC, prostate cancer; PPPY, per patient per year; USD, US dollars.

Limitations

- The claims-based database may contain inaccuracies, and patient histories may be incomplete
- Cost estimates relied on Komodo's proprietary algorithms and may not reflect actual costs incurred
- Defining treatment cohorts with a 6-week post-index window may introduce immortal-time bias, particularly in the ARPI plus chemotherapy subgroup

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Prostate Cancer

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