Real-World Economic Burden of Patients with Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Deborah R. Kaye[1], Ibrahim Khilfeh[2], Erik Muser[2], Laura Morrison[3], Ana Urosevic[3], Frederic Kinkead[3], Patrick Lefebvre[3], Dominic Pilon[3], Daniel J. George[1]

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KEY TAKEAWAY

Though the costs associated with treatment for patients with mCSPC can be high, the current study shows that the economic burden of metastatic progression itself is substantial, as reflected in the high incremental PC-related HRU and costs following metastasis yet before the initiation of therapy, with a slight decline in costs after treatment initiation

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CONCLUSIONS

- In this real-world study of patients with mCSPC in US clinical practice, over half of the patients continued treatment with ADT monotherapy despite the availability of advanced therapies and prior research showing improved overall survival, relative to ADT monotherapy

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BACKGROUND

- Androgen deprivation therapy (ADT) via surgical or medicinal castration has long been a key component in the standard of care for localized and metastatic prostate cancer (PC);[1,2] however, the annual progression rate to metastatic disease despite ADT is estimated to be nearly 35% in the US[3]
- The treatment landscape for PC has recently evolved with advanced therapies that have been approved for the treatment of patients with metastatic castration sensitive PC (mCSPC), including androgen-receptor signaling inhibitors (ARSIs; e.g., apalutamide, abiraterone acetate with prednisone, enzalutamide) which have demonstrated improved clinical outcomes compared to ADT alone in clinical trials[4,5]
- Importantly, these advanced therapies have been shown to slow progression to castration resistance among patients with mCSPC[6]
- Previous real-world studies in the US have demonstrated substantial increases in healthcare resource utilization (HRU) and costs once patients progress from localized PC to mCSPC[7]
- Given the updated treatment landscape and the promising clinical benefits associated with advanced therapies, there is a need for a contemporary characterization of the real-world HRU and economic burden among patients diagnosed with mCSPC

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OBJECTIVES

- To describe treatment patterns, HRU, and costs among patients with mCSPC treated with ADT monotherapy or advanced therapies

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METHODS (1 of 5)

Data Source

- Electronic medical record (EMR) data from the Flatiron Metastatic PC Core Registry (1 January 2013 – 1 December 2021) was used to identify patients' demographic and clinical characteristics
- Anonymized patient-level payer medical and pharmacy claims data from Komodo's Healthcare Map (1 January 2014 – 1 December 2021) were linked to Flatiron EMR data to assess HRU and costs
  - The linkage was conducted by Datavant using their patent-pending machine learning validated de-identification technology[8]
- Costs from a payer's perspective were not always available; when unavailable, Komodo used an algorithm to impute costs[9]
- Data were de-identified and Health Insurance Portability and Accountability Act (HIPAA)-compliant

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METHODS (2 of 5)

Study Design

- A retrospective, longitudinal cohort study was conducted among patients who were treated with ADT monotherapy or advanced therapy for mCSPC (**Figure 1**)
  - Patients in the advanced therapy subgroup were those who initiated their first advanced Flatiron oncologist-defined line of therapy (LOT; i.e., ARSIs, chemotherapies, estrogens, immunotherapies, poly [ADP-ribose] polymerase [PARP] inhibitors, and radiopharmaceuticals) on or after the date of mCSPC diagnosis in 2017 or later
- For patients treated with ADT monotherapy, the index date was set as the date of the first claim in Komodo Health for an ADT agent in the absence of a claim in Komodo Health or record in Flatiron for advanced therapy for mCSPC anytime
- For patients receiving advanced therapy for mCSPC, the index date was set as the earliest between: the first observed claim in Komodo Health for the mCSPC therapy or the Flatiron-defined LOT start date
- Within the 12-month baseline period, the mCSPC pre-treatment period was defined as the portion of the 12-month baseline period that occurred after evidence of metastasis and before the initiation of therapy
  - It was possible for patients to not contribute time to the mCSPC pre-treatment period if the first evidence of metastasis occurred on the index date

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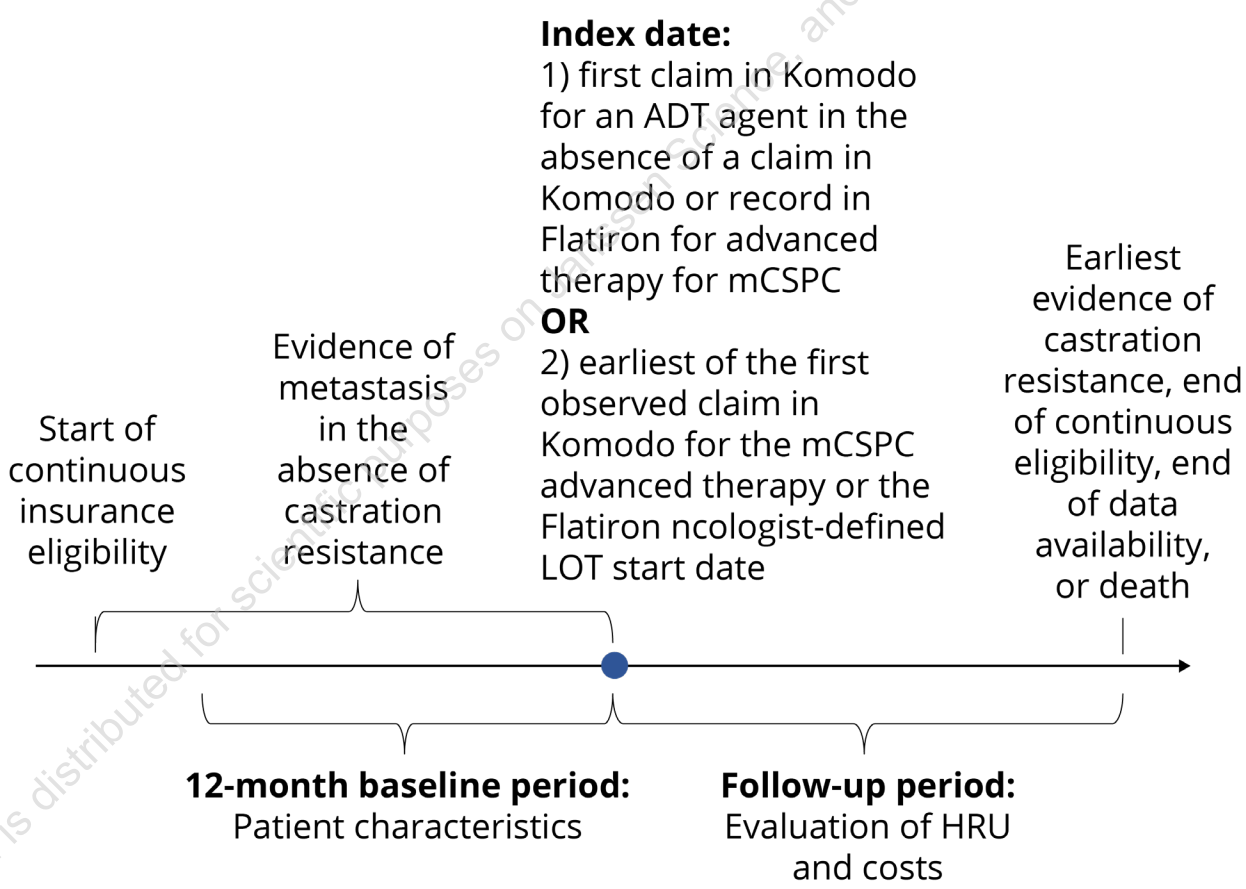
FIGURE 1: Study design scheme



ADT: androgen deprivation therapy; HRU: healthcare resource utilization; LOT: line of therapy; mCSPC: metastatic castration-sensitive prostate cancer.

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FIGURE 2: Identification of the study population

ADT: androgen deprivation therapy; ARSIs: androgen receptor signaling inhibitors; EMR: electronic medical records; LOT: line of therapy; mCRPC: metastatic castration-resistant prostate cancer; mCSPC: metastatic castration-sensitive prostate cancer; PARP: poly ADP-ribose polymerase; PC: prostate cancer.

Notes:

1. Medications considered as advanced treatment for mCSPC therapy were: ARSIs (i.e., apalutamide, darolutamide, enzalutamide, abiraterone acetate), chemotherapy (i.e., cabazitaxel, carboplatin, cisplatin, docetaxel, etoposide, mitoxantrone), PARP inhibitors (i.e., niraparib, olaparib, rucaparib, talazoparib), immunotherapy (i.e., sipuleucel-T, pembrolizumab), estrogens (i.e., estramustine phosphate, diethystillbestrol, polyestradiol phosphate), radiopharmaceuticals (i.e., radium-223, lutetium-177-PSMA-617).
2. Records for medications used as advanced treatment for mCSPC were evaluated in the Flatiron oncologist-defined LOT tables, as well as medication orders, administrations, and oral tables.
3. Patients with clinical trial medication were excluded.

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METHODS (5 of 5)

Outcomes and Statistical Analysis

- The following outcomes were measured during baseline (overall and during the mCSPC pre-treatment period) and follow-up periods, separately:
  - All-cause and PC-related HRU and costs (2022 US dollars [USD]) per-patient-per-month (PPPM) from Komodo Health closed claims
- Treatment utilization (i.e., ADT, ARSIs, first-generation antiandrogens, chemotherapy, immunotherapy) defined based on a record in Flatiron EMR data was reported during the baseline period and on the index date
- Outcomes were described using means, medians, and standard deviations (SDs) for continuous variables, and frequencies and proportions for categorical variables

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RESULTS (1 of 6)

Baseline Characteristics

TABLE 1: Baseline demographic and clinical characteristics

- Overall, 871 patients with mCSPC were included in the study, among them a subgroup of 453 patients (52.0%) were treated with ADT monotherapy while a subgroup of 418 patients (48.0%) initiated advanced therapy

	Overall cohort N=871	Advanced therapy subgroup n=418
Age at index date, years, mean ± SD [median]	**70.6 ± 9.3 [71.0]**	**67.6 ± 9.0 [67.0]**
Race, n (%)		
White	489 (56.1)	234 (56.0)
Black	114 (13.1)	60 (14.4)
Other	170 (19.5)	80 (19.1)
Unknown	98 (11.3)	44 (10.5)
Practice type, n (%)		
Community	781 (89.7)	376 (90.0)
Academic	85 (9.8)	40 (9.6)
Both	5 (0.6)	2 (0.5)
Insurance plan type, n (%)		
Commercial	370 (42.5)	222 (53.1)
Medicare	418 (48.0)	155 (37.1)
Medicaid	83 (9.5)	40 (9.6)
VA	0 (0.0)	1 (0.2)
Stage at initial PC diagnosis, n (%)		
Localized PC	357 (41.0)	129 (30.9)
mCSPC	514 (59.0)	289 (69.1)
Year of index date, n (%)		
2017	258 (29.6)	59 (14.1)
2018	175 (20.1)	83 (19.9)
2019	158 (18.1)	94 (22.5)
2020	158 (18.1)	102 (24.4)
2021	121 (13.9)	79 (18.9)
Time from PC diagnosis to mCSPC, months, mean ± SD [median]	**37.5 ± 67.7 [0.0]**	**24.3 ± 53.7 [0.0]**
Time between mCSPC and index date, months, mean ± SD [median]	**6.1 ± 10.7 [1.7]**	**4.5 ± 8.9 [1.7]**
Most recent ECOG performance score,[1] n (%)	**495 (56.8)**	**274 (65.6)**
0	242 (48.9)	149 (54.4)
1	173 (34.9)	91 (33.2)
2	63 (12.7)	26 (9.5)
3	14 (2.8)	7 (2.6)
4	3 (0.6)	1 (0.4)
Gleason score at initial PC diagnosis, n (%)		
≤6	50 (5.7)	10 (2.4)
7	137 (15.7)	48 (11.5)
8	132 (15.2)	68 (16.3)
9	237 (27.2)	140 (33.5)
10	51 (5.9)	37 (8.9)
Not available	264 (30.3)	115 (27.5)
Patients progressing to castration resistance, n (%)	**299 (34.3)**	**111 (26.6)**
Time between mCSPC and castration resistance, months, mean ± SD [median]	16.6 ± 13.3 [12.6]	15.0 ± 9.3 [13.1]
≤1 month, n (%)	4 (1.3)	0 (0.0)
>1 to ≤3 months, n (%)	10 (3.3)	4 (3.6)
>3 to ≤6 months, n (%)	28 (9.4)	9 (8.1)
>6 to ≤12 months, n (%)	101 (33.8)	35 (31.5)
>12 months, n (%)	156 (52.2)	63 (56.8)
Evidence of prior ADT use,[2] n (%)	**567 (65.1)**	**311 (74.4)**

ADT: androgen deprivation therapy; ECOG: Eastern Cooperative Oncology Group; mCSPC: metastatic castration-sensitive prostate cancer; PC: prostate cancer; SD: standard deviation; VA: Veterans Affairs.

Notes:

1. ECOG scores were considered at any time prior to and including the index date.
2. Evidence of prior ADT use was defined as any ADT at any time prior to (and excluding) the index date.

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Healthcare Resource Utilization

TABLE 2: Baseline and follow-up HRU PPPM

- During the baseline period, in the overall cohort, 31.2% of patients had a PC-related inpatient admission for a mean length of admission of 13.3 days (mCSPC pre-treatment period: 12.8 days) and 93.6% of patients had a PC-related outpatient visit for a mean of 0.7 days PPPM (**Table 2**)
- During the follow-up period, in the overall cohort, 37.9% of patients had a PC-related inpatient admission for a mean length of admission of 17.1 days and 97.6% of patients had a PC-related outpatient visit for a mean of 1.8 days PPPM
- Similar trends in PC-related HRU were observed in the advanced therapy subgroup

Mean ± SD [median] or n (%)	Overall cohort			Advanced therapy subgroup		
	Baseline		Follow-up[2]	Baseline		Follow-up[2]
	Overall N=871	mCSPC pre-treatment period[1] n=863	Overall N=871	Overall n=418	mCSPC pre-treatment period[1] n=415	Overall n=418
Length of period, months	**12.0 ± 0.0 [12.0]**	**3.7 ± 4.2 [1.7]**	**14.9 ± 12.6 [11.2]**	**12.0 ± 0.0 [12.0]**	**3.0 ± 3.4 [1.7]**	**14.5 ± 11.2 [12.0]**
All-cause **Inpatient admissions**						
≥1 inpatient admission	394 (45.2)	211 (24.4)	**394 (45.2)**	195 (46.7)	104 (25.1)	**193 (46.2)**
No. of days per admission	9.50 ± 11.92 [6.00]	10.79 ± 17.22 [6.00]	**13.92 ± 25.41 [7.00]**	8.72 ± 11.07 [5.00]	10.44 ± 19.68 [5.38]	**14.31 ± 25.96 [8.00]**
Emergency room visits						
≥1 emergency room visit	318 (36.5)	118 (13.7)	**307 (35.2)**	160 (38.3)	59 (14.2)	**143 (34.2)**
No. of days with visits	0.06 ± 0.13 [0.00]	0.09 ± 0.38 [0.00]	**0.06 ± 0.18 [0.00]**	0.07 ± 0.15 [0.00]	0.10 ± 0.38 [0.00]	**0.06 ± 0.17 [0.00]**
Outpatient visits						
≥1 outpatient visit	865 (99.3)	819 (94.9)	**859 (98.6)**	416 (99.5)	396 (95.4)	**413 (98.8)**
No. of days with visits	1.97 ± 1.49 [1.59]	4.81 ± 4.89 [3.95]	**2.92 ± 2.60 [2.40]**	1.93 ± 1.48 [1.50]	4.77 ± 3.79 [4.13]	**3.17 ± 2.87 [2.59]**
PC-related[3] **Inpatient admissions**						
≥1 inpatient admission	272 (31.2)	166 (19.2)	**330 (37.9)**	135 (32.3)	81 (19.5)	**169 (40.4)**
No. of days per admission	13.31 ± 21.45 [7.00]	12.76 ± 19.57 [7.00]	**17.08 ± 28.59 [9.00]**	11.66 ± 15.52 [6.00]	11.94 ± 21.89 [6.00]	**16.50 ± 27.78 [9.00]**
Emergency room visits						
≥1 emergency room visit	56 (6.4)	41 (4.8)	**113 (13.0)**	32 (7.7)	22 (5.3)	**59 (14.1)**
No. of days with visits	0.01 ± 0.04 [0.00]	0.03 ± 0.24 [0.00]	**0.02 ± 0.11 [0.00]**	0.01 ± 0.05 [0.00]	0.04 ± 0.28 [0.00]	**0.03 ± 0.13 [0.00]**
Outpatient visits						
≥1 outpatient visit	815 (93.6)	780 (90.4)	**850 (97.6)**	393 (94.0)	381 (91.8)	**408 (97.6)**
No. of days with visits	0.73 ± 0.78 [0.50]	3.14 ± 3.91 [2.31]	**1.79 ± 1.98 [1.40]**	0.76 ± 0.78 [0.58]	3.39 ± 3.26 [2.90]	**2.08 ± 2.06 [1.66]**

ARSI: androgen receptor signaling inhibitors; HRU: healthcare resource utilization; ICD-10-CM: International Classification of Diseases 10th Revision Clinical Modification; LHRH: luteinizing hormone-releasing hormone; mCSPC: metastatic castration-sensitive prostate cancer; No.: number; PARP: poly ADP-ribose polymerase; PC: prostate cancer; PPPM: per-patient per-month; SD: standard deviation.

Notes:

1. The mCSPC pre-treatment period was defined as the portion of the 12-month baseline period that occurred on and after evidence of metastasis but prior to the initiation of therapy.
2. The overall follow-up period was defined as the time from the index date until the earliest of i) evidence of castration resistance, ii) end of continuous insurance eligibility, iii) end of data availability, or iv) death (if available).
3. PC-related HRU and costs were identified with the ICD-10-CM code C61 and procedure codes for LHRH or of the following guideline-recommended therapies for mCSPC: ARSIs, chemotherapy, PARP inhibitors, immunotherapy, estrogens, and radiopharmaceuticals.

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Healthcare Costs

- During the baseline period, mean all-cause costs for patients in the overall cohort were $2,551 PPPM (mCSPC pre-treatment period: $6,979) and PC-related costs were $839 PPPM (mCSPC pre-treatment period: $3,825; **Figure 3**)
- During the follow-up period, mean all-cause costs PPPM increased to $5,950, mostly driven by an increase in PC-related costs, which increased to $4,363 following mCSPC therapy initiation or treatment with ADT monotherapy
- Among patients in the advanced therapy subgroup, mean all-cause costs during the baseline period were $2,334 PPPM (mCSPC pre-treatment period: $6,972) with PC-related costs of $964 PPPM (mCSPC pre-treatment period: $4,369)
- In patients in the advanced therapy subgroup, mean all-cause costs during the follow-up period were $8,829 PPPM with PC-related costs of $7,232 PPPM

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Treatment Patterns

- Among the overall cohort, the most common index treatments were leuprolide (43.7%), abiraterone acetate (20.2%), docetaxel (15.3%), enzalutamide (7.1%), and degarelix (5.6%), which were initiated as monotherapy (**Table 3**)
- In the advanced therapy subgroup, the most common index treatments were abiraterone acetate (42.1%), docetaxel (31.8%), enzalutamide (14.8%), and apalutamide (6.0%), which were initiated as monotherapy (**Table 3**)

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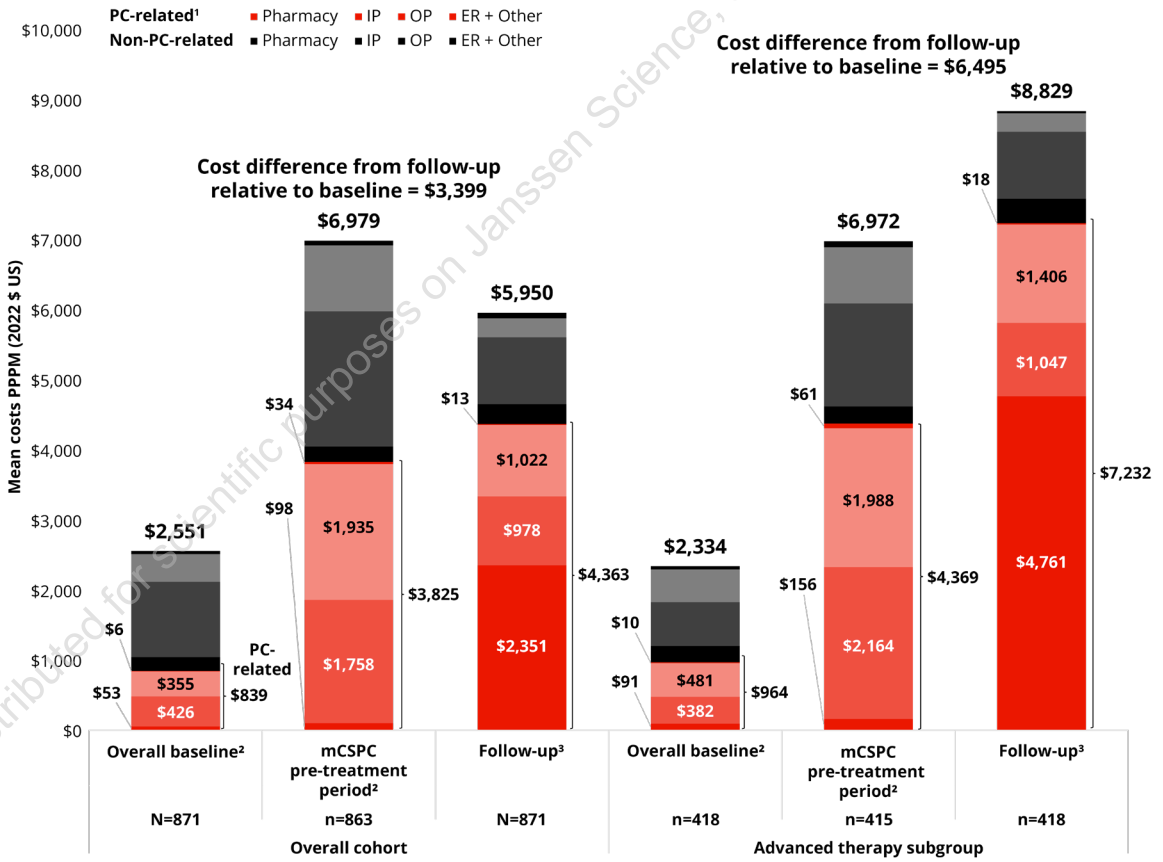
FIGURE 3: Baseline and follow-up costs PPPM



ARSI: androgen receptor signaling inhibitor; ER: emergency room; IP: inpatient; LHRH: luteinizing hormone-releasing hormone; OP: outpatient; mCSPC: metastatic castration-sensitive prostate cancer; PARP: poly ADP-ribose polymerase; PPPM: per-patient-per-month; US: United States.

Notes:

1. PC-related HRU and costs were identified with the ICD-10-CM code C61 and procedure codes for LHRH or of the following guideline-recommended therapies for mCSPC: ARSIs, chemotherapy, PARP inhibitors, immunotherapy, estrogens, and radiopharmaceuticals.
2. The mCSPC pre-treatment period was defined as the portion of the 12-month baseline period that occurred on and after evidence of metastasis but prior to the initiation of therapy.
3. The follow-up period was defined as the time from the index date until the earliest of i) evidence of castration resistance, ii) end of continuous insurance eligibility, iii) end of data availability, or iv) death (if available).

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Real-World Economic Burden of Patients with Metastatic Castration-Sensitive Prostate Cancer (mCSPC)

Deborah R. Kaye, Ibrahim Khilfeh, Erik Muser, Laura Morrison, Ana Urosevic, Frederic Kinkead, Patrick Lefebvre, Dominic Pilon, Daniel J. George

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TABLE 3: Baseline and index treatment patterns

	Overall cohort N=871		Advanced therapy subgroup n=418	
n (%)	Baseline[1]	Index treatment[2]	Baseline[1]	Index treatment[2]
ADT	**223 (25.6)**	**453 (52.0)**	**126 (30.1)**	**0 (0.0)**
Leuprolide	196 (22.5)	381 (43.7)	113 (27.0)	0 (0.0)
Degarelix	22 (2.5)	49 (5.6)	10 (2.4)	0 (0.0)
Other ADT	15 (1.7)	23 (2.6)	7 (1.6)	0 (0.0)
ARSI	**154 (17.7)**	**263 (30.2)**	**154 (36.8)**	**263 (62.9)**
Abiraterone acetate	106 (12.2)	176 (20.2)	106 (25.4)	176 (42.1)
Enzalutamide	38 (4.4)	62 (7.1)	38 (9.1)	62 (14.8)
Apalutamide	14 (1.6)	25 (2.9)	14 (3.3)	25 (6.0)
Darolutamide	1 (0.1)	0 (0.0)	1 (0.2)	0 (0.0)
First-generation antiandrogens	**413 (47.4)**	**0 (0.0)**	**216 (51.7)**	**0 (0.0)**
Bicalutamide	412 (47.3)	0 (0.0)	216 (51.7)	0 (0.0)
Chemotherapy	**3 (0.3)**	**134 (15.4)**	**3 (0.7)**	**134 (32.1)**
Docetaxel	2 (0.2)	133 (15.3)	2 (0.5)	133 (31.8)
Etoposide	1 (0.1)	0 (0.0)	1 (0.2)	0 (0.0)
Cisplatin	0 (0.0)	1 (0.1)	0 (0.0)	1 (0.2)
Immunotherapy	**0 (0.0)**	**5 (0.6)**	**0 (0.0)**	**5 (1.2)**
Sipuleucel-T	0 (0.0)	4 (0.5)	0 (0.0)	4 (1.0)
Pembrolizumab	0 (0.0)	1 (0.1)	0 (0.0)	1 (0.2)
Combination therapy[3]	-	**16 (1.8)**	-	**16 (3.8)**

ADT: androgen deprivation therapy; ARSI: androgen receptor signaling inhibitor.
Notes:
1. Treatments during the baseline period are not mutually exclusive.
2. Treatments used on the index date are mutually exclusive and were used as monotherapy unless specified otherwise.
3. Combination therapy includes ARSI+Chemotherapy, ARSI+Other, and Chemotherapy+Chemotherapy.

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This study included a large proportion of patients with de novo mCSPC and did not include patients with mCSPC who were not treated with either ADT monotherapy or advanced therapies, which may have limited the generalizability of study results. Since costs were not always available in Komodo Health data (approximately 30% of claims had missing costs), Komodo imputed missing costs, which may not have represented true costs incurred by payers. Although this study highlights major economic implications associated with mCSPC, these results may still underestimate the financial burden with the increased use of newer triplet regimens in mCSPC (i.e., abiraterone acetate or darolutamide + ADT + docetaxel). The study findings may not be generalizable to the entire population of patients with mCSPC in the US since the data sources represented the community and academic oncology perspective and administrative claims data.

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D.R. Kaye and D.J. George have received consulting fees from Janssen Scientific Affairs, LLC. I. Khilfeh is an employee of Janssen Scientific Affairs, LLC. and stockholder of Johnson & Johnson. E. Muser was an employee of Janssen Scientific Affairs, LLC at the time the study was conducted. L. Morrison, A. Urosevic, F. Kinkead, P. Lefebvre, and D. Pilon are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Janssen Scientific Affairs, LLC.

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