Real-World Economic Burden Pre- and Post-Progression to Metastatic Castration-Resistant Prostate Cancer (mCRPC) and After First-line mCRPC Therapy Initiation

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BACKGROUND

- Despite the integral role of androgen deprivation therapy (ADT) in helping to lower prostate specific antigen (PSA) levels and minimize metastasis,[1] patients with prostate cancer (PC) typically progress to metastatic castration-resistant PC (mCRPC) a disease stage that has poor prognosis and represents a significant clinical challenge for treatment[2]
- In addition to the increased complexity of clinical management, previous real-world studies have shown a significant increase in the economic burden once patients progress to mCRPC[3-6]
- However, these studies have relied on claims-based algorithms for the identification of mCRPC, which may have resulted in disease stage misclassification due to the absence of clinical data confirming disease progression, complicating the ability to accurately quantify the incremental economic burden of mCRPC[7]
- Since the approval of androgen receptor signaling inhibitors (ARSIs)[8-11] and poly (ADP-ribose) polymerase (PARP) inhibitors[8,10,12] to treat mCRPC, there is limited real-world evidence combining clinical data and payer claims to characterize the economic burden pre-and post-progression to mCRPC as well as after the initiation of first-line (1L) therapy among patients with mCRPC in the United States from a payer perspective

OBJECTIVES

- To describe healthcare resource utilization (HRU) and costs of patients pre- and post-progression to mCRPC as well as after 1L mCRPC therapy initiation

METHODS

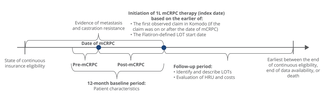
Data source

- Electronic medical record (EMR) data from the Flatiron Metastatic PC Core Registry (1 January 2013 – 31 December 2021) was used to identify patients' demographic and clinical characteristics
- Claims data from the Komodo Healthcare Map records de-identified healthcare encounters, consisting of anonymized patient-level pharmacy and medical claims (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 to create patient-specific tokens in Komodo and Flatiron data sources, allowing linking without sharing underlying patient information[13]
- Within Komodo, paid amounts were available for pharmacy claims while costs were not always directly available for medical claims
  - Komodo used an algorithm to impute costs from a payer's perspective, derived based on several factors, including type of claim, payer channel, type of service, and setting of care[14]
- Data are de-identified and Health Insurance Portability and Accountability Act (HIPAA) compliant
- Flatiron Health, Inc., Komodo Health Solutions, and Datavant did not participate in data analyses

Study design

- A retrospective longitudinal cohort study design was used
- The index date was defined as the initiation of the Flatiron-defined 1L mCRPC therapy, more specifically:
  - A line of therapy (LOT) for mCRPC consisted of treatment with an ARSI, chemotherapy, an estrogen, immunotherapy, a PARP inhibitor, or a radiopharmaceutical. Flatiron-defined LOTs were numbered such that the 1L was defined as the one initiated on or after mCRPC diagnosis
  - The index date was defined as the earliest of:
    - The first observed claim in Komodo for an agent included as part of 1L mCRPC therapy (if the claim was on or after the date of mCRPC)
    - The Flatiron-defined LOT start date
- Baseline demographic and clinical characteristics were evaluated in the 12 months preceding the index date using both Flatiron EMR data and closed claims in Komodo
  - The 12-month baseline period was stratified into two periods (i.e., pre-mCRPC and post-mCRPC); patients could contribute patient time to one or both time periods
    - The pre-mCRPC period was defined as the portion of the 12-month baseline period that occurred prior to the latest of metastasis or castration resistance (i.e., during localized PC, non-metastatic CRPC [nmCRPC] or metastatic castration-sensitive PC [mCSPC])
    - The post-mCRPC period was defined as the portion of the 12-month baseline period that occurred on and after the latest of metastasis or castration resistance and before the initiation of 1L therapy
- HRU and costs were assessed using closed claims (payer complete) in Komodo and were evaluated during the 12-month baseline period (stratified by pre- and post-mCRPC) and during the follow-up period (stratified by 1L, second-line [2L], third-line [3L], and overall)
  - The overall follow-up period was defined as the time from the index date until the earliest of i) end of continuous insurance eligibility, ii) end of data availability, or iii) death (if available)
    - 1L therapy period was defined as the time from the index date to the earliest of i) the Flatiron-defined end of 1L, ii) the end of the overall follow-up
    - 2L and 3L therapy periods were defined as the time from the Flatiron-defined start of the given LOT until the earliest of i) the Flatiron-defined end of the given LOT (if available), ii) the end of the overall follow-up
    - 2L and 3L HRU and costs were reported among patients with ≥1 claim in Komodo closed claims for an agent included as part of patients 2L and 3L regimens, respectively, as identified in Flatiron

FIGURE 1: Study design scheme

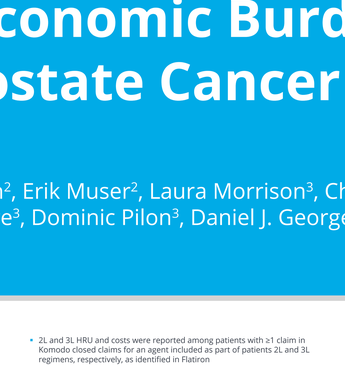


1L: first-line; HRU: Healthcare resource utilization; LOT: line of therapy; mCRPC: metastatic castration-resistant prostate cancer.
Data Source: Flatiron Metastatic PC Core Registry (January 2013 - December 2021), Komodo Health Solutions (January 2014 - December 2021)

Patient selection criteria

- Patients were included if they met the following criteria:
  - A chart-confirmed diagnosis of metastatic PC
  - Confirmed CRPC
    - Based on Flatiron algorithm incorporating i) physician reported CRPC in medical chart, ii) observed rising PSA values while on hormone therapy, or iii) physician documented rising PSA on hormone therapy plus a change in treatment
  - ≥1 LOT on or after mCRPC diagnosis and January 1, 2017 (selected to report outcomes among patients initiated on more recently approved regimens for the treatment of mCRPC)
  - ≥1 claim in Komodo closed claims for an agent included as part of patients 1L regimen initiated on or after mCRPC diagnosis identified in Flatiron
  - ≥12 months of continuous insurance eligibility in Komodo closed claims data prior to the index date
- Patients were excluded from the study if they used a clinical trial medication as part of 1L therapy for mCRPC

FIGURE 2: Patient identification flowchart



1L: first-line; ARSIs: androgen receptor signaling inhibitors; CRPC: castration-resistant prostate cancer; EMR: electronic medical records; LOT: line of therapy; mCRPC: metastatic castration-resistant prostate cancer; PARP: poly ADP-ribose polymerase; PC: prostate cancer.
Notes:
† Medications considered for 1L mCRPC therapy were: ARSIs (i.e., apalutamide, darolutamide, enzalutamide, abiraterone acetate), chemotherapy (i.e., cabazitaxel, carboplatin, cisplatin, docetaxel, mitoxantrone), PARP inhibitors (i.e., olaparib, rucaparib, talazoparib), immunotherapy (i.e., sipuleucel-T, pembrolizumab), estrogens (i.e., estramustine phosphate, diethylstilbestrol, polyestradiol phosphate), radiopharmaceuticals (i.e., radium-223, lutetium-177-PSMA-617).

Outcomes

- LOTs were evaluated using Flatiron EMR data and regimens used as 1L, 2L, and 3L therapy for mCRPC were reported
- HRU and healthcare costs were assessed using closed claims in Komodo and were reported by category, including inpatient, outpatient, emergency room (ER) and other services
- Healthcare cost categories also included medical costs (i.e., sum of inpatient, ER, outpatient and other costs), pharmacy costs and total healthcare costs (sum of medical and pharmacy costs)
  - PC-related HRU and costs were defined based on claims for malignant neoplasm of prostate (identified by an International Classification of Diseases, Tenth Revision, Clinical Modification [ICD-10-CM] diagnosis code C61), or a claim with a procedure code for luteinizing hormone-releasing hormone (LHRH) or other guideline-recommended therapies for mCRPC
- All outcomes were reported per-patient-per-month (PPPM), and costs were expressed in 2021 US dollars; healthcare costs were measured from a payer's perspective

RESULTS

Baseline characteristics

- A total of 459 patients with mCRPC were identified; mean age was 70.0 years and most patients (57.1%) were White while 15.5% were Black
- Most patients were either commercially (44.9%) or Medicare (43.4%) insured
- The mean (median) time between initial PC diagnosis obtained through abstraction and confirmed mCRPC status was 63.8 (31.0) months in Flatiron EMR
- The mean (median) time between mCRPC diagnosis and the initiation of 1L mCRPC therapy was 3.8 (1.2) months
  - The mean (median) duration of the pre-mCRPC baseline period was 10.0 (10.9) months (n= 416)
  - The mean (median) duration of the post-mCRPC baseline period was 3.3 (3.3) months (n= 400)
- Immediately prior to progressing to mCRPC, 364 (79.3%) patients were mCSPC, 91 (19.8%) patients were nmCRPC and 4 (0.9%) patients were localized PC
- Visceral metastases were observed in 16.1% of patients
- Most patients had used other therapies prior to 1L mCRPC therapy initiation, with 429 (93.5%) patients having evidence of prior ADT use, 145 (31.6%) patients having prior first-generation anti-androgen use, 257 (56.0%) patients having prior ARSI use, and 41 (8.9%) of patients having prior chemotherapy use

TABLE 1: Baseline characteristics

	mCRPC N=459
Age, mean ± SD [median]	**70.0 ± 9.3 [70.0]**
Race, n (%)	
White	262 (57.1)
Black	71 (15.5)
Other	87 (19.0)
Unknown	31 (6.8)
Insurance plan type, n (%)	
Commercial	206 (44.9)
Medicare	199 (43.4)
Medicaid	54 (11.8)
Stage at initial PC diagnosis, n (%)	
Localized PC	241 (52.5)
mCSPC	218 (47.5)
Disease stage directly preceding mCRPC diagnosis, n (%)	
mCSPC	364 (79.3)
nmCRPC	91 (19.8)
Localized PC	4 (0.9)
Year of index date, n (%)	
2017	116 (25.3)
2018	106 (23.1)
2019	78 (17.0)
2020	94 (20.5)
2021	65 (14.2)
Time from PC diagnosis to 1L therapy initiation, months, mean ± SD [median]	**63.8 ± 72.3 [31.0]**
Time from mCRPC diagnosis to 1L therapy initiation, months, mean ± SD [median]	**3.8 ± 6.6 [1.2]**
Prior evidence of ADT use,[1] n (%)	**429 (93.5)**
Prior anti-androgen use,[2] n (%)	**331 (72.1)**
First-generation anti-androgens	145 (31.6)
ARSIs	257 (56.0)
Abiraterone acetate	157 (34.2)
Enzalutamide	116 (25.3)
Apalutamide	20 (4.4)
Darolutamide	5 (1.1)
Prior chemotherapy use,[2] (%)	**41 (8.9)**

1L: first-line; ADT: androgen deprivation therapy; ARSI: androgen receptor signaling inhibitors; mCRPC: metastatic castration-resistant prostate cancer; mCSPC: metastatic castration-sensitive prostate cancer; nmCRPC: non-metastatic castration-resistant prostate cancer; PC: prostate cancer; SD: standard deviation.
Notes:
1. Prior evidence of ADT use was defined as any ADT at any time prior to (and excluding) the index date.
2. Evaluated in the 12 month baseline period.

HRU and costs

Baseline

- During the full 12-month baseline period, patients averaged 1.18 days PPPM with all-cause inpatient admissions (pre-mCRPC: 1.18 post-mCRPC: 1.57) and 2.68 days PPPM with all-cause outpatient visits (pre-mCRPC: 2.56; post-mCRPC: 4.94)
- Patients averaged 0.98 days PPPM with PC-related inpatient admissions during the full 12-month baseline period (pre-mCRPC: 0.96; post-mCRPC: 1.49) and 1.49 days PPPM with PC-related outpatient visits (pre-mCRPC: 1.34; post-mCRPC: 3.67)

TABLE 2: Baseline and follow-up HRU PPPM

	Baseline			Follow-up			
Mean ± SD [median]	**Overall N=459**	**Pre-mCRPC N=416**	**Post-mCRPC N=400**	**Overall[a] N=459**	**1L[a] N=459**	**2L[a] N=166**	**3L[a] N=86**
Length of period, months	**12.0 ± 0.0 [12.0]**	**10.0 ± 2.4 [10.9]**	**3.3 ± 3.0 [3.3]**	**10.2 ± 11.0 [12.0]**	**8.5 ± 8.2 [5.4]**	**6.5 ± 5.7 [5.1]**	**5.2 ± 4.9 [3.2]**
All-cause							
Inpatient admissions							
No. of admissions	0.11 ± 0.24 [0.00]	0.11 ± 0.25 [0.00]	0.15 ± 0.49 [0.00]	0.26 ± 0.80 [0.09]	0.15 ± 0.36 [0.00]	0.21 ± 0.59 [0.00]	0.17 ± 0.32 [0.00]
No. of days	1.18 ± 3.45 [0.00]	1.18 ± 3.72 [0.00]	1.57 ± 5.19 [0.00]	2.83 ± 5.37 [0.40]	2.05 ± 5.35 [0.00]	2.53 ± 6.22 [0.00]	2.00 ± 5.02 [0.00]
Emergency room visits							
No. of days with visits	0.07 ± 0.17 [0.00]	0.07 ± 0.18 [0.00]	0.17 ± 1.56 [0.00]	0.10 ± 0.25 [0.00]	0.09 ± 0.28 [0.00]	0.10 ± 0.26 [0.00]	0.07 ± 0.25 [0.00]
Outpatient visits							
No. of days with visits	2.68 ± 2.21 [2.26]	2.56 ± 2.28 [2.24]	4.94 ± 5.42 [3.72]	3.38 ± 2.97 [2.88]	3.75 ± 3.63 [2.88]	3.94 ± 2.57 [3.34]	5.33 ± 4.98 [3.91]
Pharmacy claims							
No. of pharmacy claims	3.25 ± 2.92 [2.42]	3.20 ± 2.96 [2.42]	4.84 ± 10.95 [2.90]	4.22 ± 3.28 [3.37]	4.44 ± 3.77 [3.59]	4.65 ± 2.88 [4.02]	5.33 ± 7.02 [3.84]
Other services							
No. of days with other services	0.03 ± 0.28 [0.00]	0.03 ± 0.28 [0.00]	0.05 ± 0.57 [0.00]	0.05 ± 0.60 [0.00]	0.06 ± 0.63 [0.00]	0.03 ± 0.23 [0.00]	0.05 ± 0.38 [0.00]
PC-related[b]							
Inpatient admissions							
No. of admissions	0.08 ± 0.17 [0.00]	0.07 ± 0.17 [0.00]	0.13 ± 0.46 [0.00]	0.22 ± 0.78 [0.06]	0.12 ± 0.29 [0.00]	0.19 ± 0.47 [0.00]	0.16 ± 0.32 [0.00]
No. of days	0.98 ± 2.87 [0.00]	0.96 ± 3.08 [0.00]	1.49 ± 5.09 [0.00]	2.57 ± 5.07 [0.25]	1.87 ± 5.04 [0.00]	2.46 ± 6.13 [0.00]	1.98 ± 4.99 [0.00]
Emergency room visits							
No. of days with visits	0.02 ± 0.08 [0.00]	0.02 ± 0.08 [0.00]	0.09 ± 0.83 [0.00]	0.04 ± 0.17 [0.00]	0.04 ± 0.21 [0.00]	0.03 ± 0.16 [0.00]	0.02 ± 0.09 [0.00]
Outpatient visits							
No. of days with visits	1.49 ± 0.96 [1.34]	1.34 ± 1.00 [1.14]	3.67 ± 4.59 [2.42]	2.35 ± 2.23 [1.87]	2.62 ± 2.84 [1.98]	2.91 ± 1.83 [2.61]	4.49 ± 4.93 [3.13]
Pharmacy claims							
No. of pharmacy claims	0.37 ± 0.45 [0.17]	0.36 ± 0.46 [0.12]	0.67 ± 2.45 [0.00]	0.61 ± 0.58 [0.51]	0.77 ± 0.70 [0.80]	0.62 ± 0.67 [0.56]	0.35 ± 0.55 [0.00]
Other services							
No. of days with other services	0.00 ± 0.00 [0.00]	0.00 ± 0.00 [0.00]	0.00 ± 0.00 [0.00]	0.00 ± 0.07 [0.00]	0.00 ± 0.03 [0.00]	0.02 ± 0.22 [0.00]	0.05 ± 0.37 [0.00]

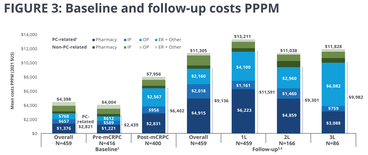
1L: first-line; 2L: second-line; 3L: third-line; ARSI: androgen receptor signaling inhibitors; HRU: Healthcare resource utilization; ICD-10-CM: International Classification of Diseases 10th Revision Clinical Modification; LHRH: luteinizing hormone-releasing hormone; LOT: line of therapy; mCRPC: metastatic castration-resistant prostate cancer; mCSPC: metastatic castration-sensitive prostate cancer; nmCRPC: non-metastatic castration-resistant prostate cancer; No.: number; PARP: poly ADP-ribose polymerase; PC: prostate cancer; PPPM: per-patient-per-month; SD: standard deviation.
Notes:
1. The pre-mCRPC period was defined as the portion of the 12-month baseline period that occurred prior to evidence of both metastasis and castration resistance. The post-mCRPC period was defined as the portion of the 12-month baseline period that occurred on and after evidence of both metastasis and castration resistance. Patients could contribute patient time to one or both time periods.
2. The 1L therapy period was defined as the time from the index date to the earliest of i) the Flatiron-defined end of 1L, ii) the end of the follow-up period, iii) end of data availability, or iii) death (if available).
3. The 1L therapy period was defined as the time from the index date to the earliest of i) the Flatiron-defined end of 1L, ii) the end of the follow-up period. The 2L and 3L therapy periods were defined as the time from the Flatiron-defined start of the given LOT until the earliest of i) the Flatiron-defined end of the given LOT (if available), ii) the end of the follow-up period.
4. 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 mCRPC: androgen ARSIs, chemotherapy, PARP inhibitors, immunotherapy, estrogens, and radiopharmaceuticals.

- During the full 12-month baseline period, patients had mean total all-cause costs PPPM of $4,398 (PC-related: $2,821)
  - Medical costs were $2,713 (PC-related: $1,445) and pharmacy costs were $1,685 (PC-related: $1,376)
- All-cause total costs PPPM nearly doubled in the post- relative to pre-mCRPC period (pre-mCRPC: $4,004; post-mCRPC: $7,956) while total PC-related costs more than doubled (pre-mCRPC: $2,439; post-mCRPC: $6,402)
  - The cost increase was driven by higher PC related medical costs, specifically outpatient costs which increased from $612 to $2,567 PPPM pre- relative to post-mCRPC

Follow-up

- The mean (median) duration of the follow-up after starting 1L treatment was 15.2 (12.3) months and the mean (median) duration of 1L mCRPC therapy was 8.5 (5.6) months
  - The 166 patients progressing to 2L mCRPC therapy, with a corresponding claim in Komodo, had a mean (median) 2L therapy duration of 6.5 (5.1) months
  - The 86 patients progressing to 3L mCRPC therapy, with a corresponding claim in Komodo, had a mean (median) 3L therapy duration of 5.2 (3.2) months
- During the overall follow-up period, patients averaged 2.83 days PPPM with all-cause inpatient admissions (1L: 2.05; 2L: 2.53; 3L: 2.00) and 3.38 days PPPM with all-cause outpatient visits (1L: 3.75.; 2L: 3.94; 3L: 5.33)
- Patients averaged 2.57 days PPPM with PC-related inpatient admissions during the overall follow-up period (1L: 1.87; 2L: 2.46; 3L: 1.98) and 2.35 days PPPM with PC-related outpatient visits (1L: 2.62.; 2L: 2.91; 3L: 4.49)
- Relative to the post-mCRPC baseline period, all-cause costs PPPM increased 66% following the initiation of 1L mCRPC therapy (post-mCRPC: $7,956; 1L: $13,211)
  - This cost increase was driven by higher PC-related pharmacy costs (post-mCRPC: $2,831; 1L: $6,223) and higher PC-related outpatient costs (post-mCRPC: $2,567; 1L: $4,100)
- After 1L mCRPC therapy, all cause costs PPPM decreased 16.4% and 10.5% relative to costs observed during 2L and 3L mCRPC therapy (2L: $11,038; 3L: $11,828)
  - This cost decrease was driven by lower PC-related pharmacy costs (1L: $6,223; 2L: $4,859; 3L: $3,088)

FIGURE 3: Baseline and follow-up costs PPPM

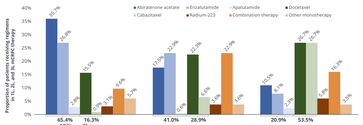


1L: first-line; 2L: second-line; 3L: third-line; ARSI: androgen receptor signaling inhibitors; ER: emergency room; IP: inpatient; LHRH: luteinizing hormone-releasing hormone; LOT: line of therapy; OP: outpatient; mCRPC: metastatic castration-resistant prostate cancer; PARP: poly ADP-ribose polymerase; PC: prostate cancer; PPPM: per-patient-per-month; US: United States.
Notes:
† 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 mCRPC: ARSIs, chemotherapy, PARP inhibitors, immunotherapy, estrogens, and radiopharmaceuticals.
2. The pre-mCRPC period was defined as the portion of the 12-month baseline period that occurred prior to evidence of both metastasis and castration resistance. The post-mCRPC period was defined as the portion of the 12-month baseline period that occurred on and after evidence of both metastasis and castration resistance. Patients could contribute patient time to one or both time periods.
3. The 1L therapy period was defined as the time from the index date to the earliest of i) the Flatiron-defined end of 1L, ii) the end of the follow-up period, iii) end of data availability, or iii) death (if available).
4. The 1L therapy period was defined as the time from the index date to the earliest of i) the Flatiron-defined end of 1L, ii) the end of the follow-up period. The 2L and 3L therapy periods were defined as the time from the Flatiron-defined start of the given LOT until the earliest of i) the Flatiron-defined end of the given LOT (if available) or ii) the end of the follow-up period.

Regimens used in LOTs

- The proportion of patients using ARSI monotherapy decreased from 1L (Overall: 65.4%; Abiraterone acetate: 35.7%; Enzalutamide: 26.8%; Apalutamide: 2.8%) to 2L (Overall: 41.0%; Abiraterone acetate: 17.5%; Enzalutamide: 22.9%; Apalutamide: 0.6%) and 3L (Overall: 20.9%; Abiraterone acetate: 10.5%; Enzalutamide: 8.1%; Apalutamide: 2.3%)
- The proportion of patients using chemotherapy monotherapy increased from 1L (Overall: 16.3%; Docetaxel: 15.5%; Cabazitaxel: 0.9%) to 2L (Overall: 28.9%; Docetaxel: 22.3%; Cabazitaxel: 6.6%) and 3L (Overall: 53.5%; Docetaxel: 26.7%; Cabazitaxel: 26.7%)

FIGURE 4: Regimens used as 1L, 2L, and 3L mCRPC therapy[1,2]



1L: first-line; 2L: second-line; 3L: third-line; ARSI: androgen receptor signaling inhibitor; Chemo: chemotherapy; mCRPC: metastatic castration-resistant prostate cancer.
Notes:
1. All individual agents reported were used as monotherapy in 1L, 2L, or 3L mCRPC therapy.
2. Medications considered for other monotherapy were: ARSIs (i.e., darolutamide), chemotherapy (i.e., cisplatin, mitoxantrone), PARP inhibitors (i.e., olaparib), and immunotherapy (i.e., pembrolizumab).

LIMITATIONS

- The Flatiron algorithm for identifying CRPC status relied on physician report or observed rising PSA values and did not incorporate an evaluation of testosterone levels; as such, the evaluation of CRPC status may be subject to misclassification or reporting inaccuracies
- Results presented in this study were obtained from two linked data sources including a database that represents the community and academic oncology perspective and an open-source healthcare claims database; as such, results may not be representative of the entire population of patients with mCRPC in the US, which may limit the generalizability of the study
- Although the Datavant Match method used for linking the two data sources has high precision, it does not guarantee perfect accuracy in correctly identifying all claims for a patient or all matches
- Cost data is not always available in Komodo Health Solutions data, with an estimate of approximately 30% of claims having missing costs; imputation for missing costs was conducted by Komodo and costs may not represent true costs incurred by payers[14]

KEY TAKEAWAY

The results of this real-world study among patients with mCRPC treated in community oncology practices and academic centers found that prior to 1L mCRPC therapy initiation, PC-related total costs post-progression to mCRPC were 2 times higher than prior to progression and 4 times higher once initiating 1L mCRPC therapy

CONCLUSIONS

Given the incremental costs associated with PC disease progression reported in this study, clinical interventions aiming to delay progression, and ultimately lower total costs, are warranted

ACKNOWLEDGEMENTS

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DISCLOSURES

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