B4

# Time burden and healthcare costs associated with docetaxel in patients with metastatic castration-sensitive prostate cancer initiating an androgen receptor pathway inhibitor-based regimen

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## Key Takeaway

During the first 12 months following initiation of an ARPI-based treatment, patients with chemotherapy intensification experienced 18% more days lost to management of mCSPC driven by days spent in the inpatient setting, and significantly greater healthcare costs, than those who were not treated with chemotherapy

## Conclusions

In this real-world study, patients initiating an intensified ARPI-based treatment with docetaxel experienced greater time burden managing mCSPC and higher healthcare costs than those initiating treatment without docetaxel

Patient counseling that includes discussion of the time burden associated with chemotherapy when included in a treatment regimen along with an ARPI and ADT should be incorporated into decision-making conversations regarding treatment selection

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**Disclosures**
D. Sentana Lledo and A.K. Morgans are employees of the Dana-Farber Cancer Institute. A. Gupta is an employee of the University of Minnesota Medical School. C. Rossi, L. Diaz, G. Wong, and D. Pilon are employees of Analysis Group, Inc., a consulting company that has provided paid consulting services to Johnson & Johnson. S. Burbage and I. Khilfeh are employees of Johnson & Johnson and stockholders of Johnson & Johnson.

## Background

- Prior to the approval of androgen receptor pathway inhibitors (ARPIs), used in combination with androgen deprivation therapy (ADT) to treat patients with metastatic castration-sensitive prostate cancer (mCSPC), chemotherapy was an important treatment option[1,2]
- Recently, intensifying treatment with a triple combination of chemotherapy (i.e., docetaxel), an ARPI (i.e., abiraterone acetate or darolutamide) and ADT has been recommended for the treatment of high-volume mCSPC[3,4]
- To date, however, there has been little data to assess the time burden and costs associated with chemotherapy-containing regimens (CCR) relative to non-chemotherapy containing regimens (NCR) used for treatment of mCSPC

## Objective

- To compare the incremental burden of the addition of docetaxel to ARPI + ADT combination therapy by assessing the number of days needed to manage prostate cancer (PC) care and healthcare costs among patients with mCSPC in the United States (US)

## Methods

### Data sources

- Clinical data from Precision Point Specialty (PPS) Analytics collected as part of routine clinical care from community-based urology practices in the US linked with administrative claims data from the Komodo Research Database (KRD; study period: 1 January 2016 - 31 December 2023)
- Data were de-identified and Health Insurance Portability and Accountability Act (HIPAA) compliant

### Study design

- A retrospective longitudinal analysis utilizing propensity score-weighted cohorts of ARPI-naïve patients with mCSPC initiated on a CCR or an NCR was conducted
- Patients were assigned to mutually exclusive treatment cohorts based on the presence or absence of a docetaxel claim 90 days prior to or 180 days after the first claim for abiraterone acetate or darolutamide
- For the CCR cohort, the index date was defined as the earliest of docetaxel initiation or first claim for abiraterone acetate or darolutamide on or after US Food and Drug Administration (FDA) mCSPC indication approval dates for abiraterone acetate (7 February 2018 [high-risk mCSPC])[5] or darolutamide (5 August 2022)[6]
- For the NCR cohort, the index date was defined as the first claim for abiraterone acetate on or after US FDA high-risk mCSPC indication approval
- Baseline patient characteristics were evaluated in the 6 months preceding the index date
- The observation period spanned from the index date until the earliest of 12 months following the index date, discontinuation of the index ARPI or initiation of a new ARPI, initiation of docetaxel (NCR cohort only), end of continuous closed claims insurance eligibility, or end of data availability (including death)

### Study outcomes

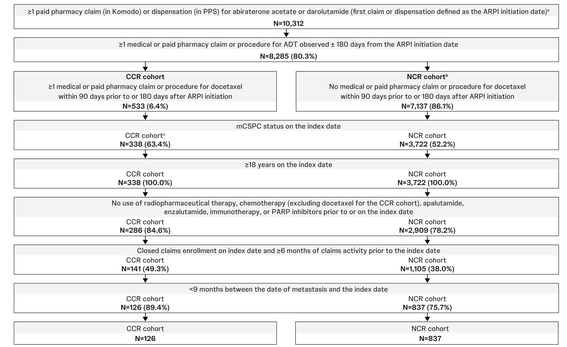
- The primary outcome was the time spent managing mCSPC, defined as the number of days with PC-related resource utilization or PC management care (i.e., imaging, biopsy, chemotherapy management, prostate-specific antigen or genetic testing)
- Secondary outcomes included all-cause and PC-related healthcare resource utilization (HRU; i.e., inpatient stays and days, days with outpatient visits, days with emergency room visits, days with other visits) and healthcare costs (i.e., sum of medical and pharmacy costs)
- All outcomes were reported per-patient-per-month (PPPM) and healthcare costs were inflated to 2023 US dollars using the medical care component of the Consumer Price Index

### Statistical analysis

- Overlap weighting, based on the propensity score (PS), was used to account for differences in baseline characteristics between the CCR and NCR cohorts[7,8]
- The PS was obtained from a logistic regression model where index treatment cohort was the dependent variable and the following baseline characteristics were independent variables: age, race, insurance type, bone metastasis, visceral metastasis, *de novo* metastasis, benign prostatic hyperplasia and PC-related medical and pharmacy costs
- Balancing of baseline characteristics between study cohorts after weighting was confirmed by standardized differences <10% which indicates balance[9]
- Weighted Poisson regression models were used to compare time managing mCSPC and HRU outcomes
- Weighted ordinary least squares regression models were used to compare cost outcomes
- All regression models were further adjusted for baseline characteristics that remained imbalanced after weighting

### Patient selection criteria

**Figure 1: Patient flowchart**




ADT: androgen deprivation therapy; ARPI: androgen receptor pathway inhibitor; CCR: chemotherapy-containing regimen; mCSPC: metastatic castration-sensitive prostate cancer; NCR: non-chemotherapy containing regimen; PARP: poly-ADP ribose polymerase; PPS: Precision Point Specialty.
**Notes:** a. ARPI initiation date on or after US FDA approval for mCSPC (i.e., 7 February 2018 for abiraterone acetate [high-risk mCSPC], 5 August 2022 for darolutamide). b. Only ARPI-naïve patients who initiated abiraterone acetate + ADT were included in the NCR cohort given darolutamide + ADT is not approved for treatment of mCSPC without the concurrent use of docetaxel. c. Patients were excluded if they became castration resistant during the time between ARPI initiation and docetaxel initiation.

## Results

### Baseline characteristics

- Overall, 126 patients with mCSPC were included in the CCR cohort and 826 patients with mCSPC were included in the NCR cohort (**Figure 1**)
- Baseline patient characteristics were generally well-balanced between the weighted cohorts (**Table 1**)

**Table 1: Baseline Characteristics**

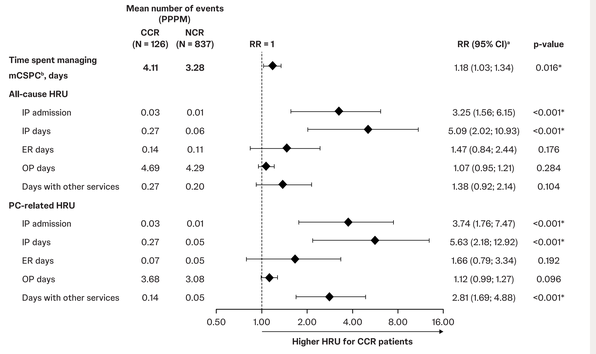
| | Weighted Population[a] | | |
|---|---|---|---|
| | CCR[b] N=126 | NCR[b] N=837 | Standardized Difference, % |
| **Age, mean ± SD [median]** | 64.7 ± 7.6 [64.5] | 64.7 ± 9.3 [63.4] | 0 |
| **Race, n (%)** | | | |
| White | 66 (52.6) | 440 (52.6) | 0 |
| Black or African American | 18 (14.4) | 121 (14.4) | 0 |
| Other | 17 (13.4) | 112 (13.4) | 0 |
| Unknown | 25 (19.6) | 164 (19.6) | 0 |
| **Geographic region, n (%)** | | | |
| South | 50 (40.1) | 295 (35.2) | 10.0 |
| Midwest | 36 (28.4) | 258 (30.9) | 5.4 |
| Northeast | 26 (21.0) | 171 (20.4) | 1.5 |
| West | 13 (10.5) | 113 (13.5) | 9.1 |
| **Payer type, n (%)** | | | |
| Commercial | 78 (61.9) | 518 (61.9) | 0 |
| Medicare | 38 (29.9) | 250 (29.9) | 0 |
| Medicaid | 10 (8.2) | 69 (8.2) | 0 |
| **Metastasis type[c], n (%)** | | | |
| Bone | 110 (87.5) | 733 (87.5) | 0 |
| Nodal | 71 (56.4) | 357 (42.7) | 27.7 |
| Visceral | 42 (33.7) | 282 (33.7) | 0 |
| ***De novo* metastasis[d], n (%)** | 99 (78.5) | 657 (78.5) | 0 |
| **Benign prostatic hyperplasia, n (%)** | 69 (54.6) | 457 (54.6) | 0 |
| **PC-related total costs (PPPM)[e], mean ± SD [median]** | 3,553 ± 4,138 [2,342] | 3,553 ± 4,349 [1,860] | 0 |

ADT: androgen deprivation therapy; CCR: chemotherapy-containing regimen; NCR: non-chemotherapy containing regimen; PC: prostate cancer; PPPM: per-patient-per-month; SD: standard deviation.
**Notes:** a. Of note, the number of patients reported in this weighted population represents the sum of weights for the corresponding non-weighted patients, rounded to the nearest integer. The proportions displayed were calculated before the rounding and may be slightly different than if they were calculated based on rounded numbers. b. The CCR cohort includes patients treated with abiraterone acetate or darolutamide, and docetaxel, and ADT. The NCR cohort includes patients treated with abiraterone acetate and ADT. c. Types of metastases were defined at any time prior to (and including) the index date. Types of metastases were not mutually exclusive. d. *De novo* metastasis was defined as ≤180 days between first observed PC diagnosis and date of metastasis. e. Healthcare costs were inflated to 2023 US dollars using the medical care component of the Consumer Price Index.

### Time spent managing mCSPC

- Patients were followed for a mean of 6.3 months in the CCR cohort and 6.8 months in the NCR cohort
- For the CCR cohort, a mean of 4.0 docetaxel infusions were observed per patient (mean time 22 days between infusions)
- The CCR cohort spent a mean of 4.1 days PPPM managing mCSPC, compared to 3.3 days PPPM in the NCR cohort (rate ratio: 1.18, 95% confidence interval [CI]: 1.03, 1.34; p=0.016) (**Figure 2**)
- The CCR cohort experienced a greater number of all-cause inpatient admissions (rate ratio: 3.25, 95% CI: 1.56, 6.15; p<0.001) and inpatient days (rate ratio: 5.09, 95% CI: 2.02, 10.93; p<0.001) compared to the NCR cohort

**Figure 2: Time spent managing mCSPC and HRU between patients receiving CCR or NCR**

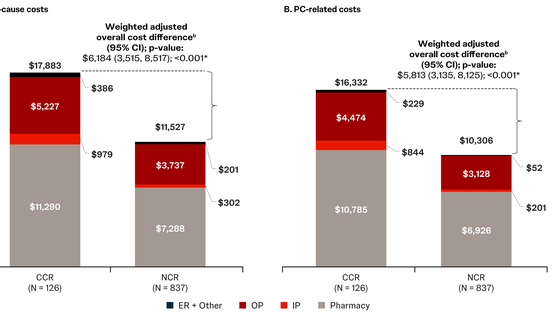



CCR: chemotherapy-containing regimen; CI: confidence interval; ER: emergency room; HRU: healthcare resource utilization; IP: inpatient; mCSPC: metastatic castration sensitive prostate cancer; NCR: non-chemotherapy containing regimen; OP: outpatient; PC: prostate cancer; PPPM: per-patient-per-month; RR: rate ratio.
*p-value < 0.05
**Notes:** a. The weighted model adjusted for the following baseline variables: all-cause pharmacy costs, categorical age (≤70, 71-80, ≥81), time between metastasis and index date, baseline time spent managing mCSPC, erectile dysfunction, nodal metastasis and Quan-Charlson comorbidity index score. b. The time spent managing mCSPC was reported from the patients' perspective. Each day with a PC-related HRU or PC management care HRU outcome. When multiple HRU services for one patient on the same day were observed, these services only contributed one day. For inpatient stays, the number of days was calculated from the admission and discharge dates. In instances where the date of the claim differed from the date the service was received (for example, laboratory tests or imaging), the date in which the service was received was used. All days were summed per person, and time spent managing mCSPC was reported PPPM.

### Economic burden

- Mean all-cause medical and pharmacy costs were $17,833 PPPM in the CCR cohort and $11,527 PPPM in the NCR cohort (cost difference [CD]: $6,184, 95% CI: 3,515, 8,517; p<0.001) (**Figure 3**)
- Mean all-cause medical costs were $6,592 PPPM in the CCR cohort and $4,240 PPPM in the NCR cohort (CD: $2,060, 95% CI: 865, 3,369; p<0.001)
- Chemotherapy management costs were $1,225 PPPM in the NCR cohort, driven largely by granulocyte-colony stimulating factor use ($920 PPPM)

**Figure 3: Healthcare costs between patients receiving CCR or NCR, PPPM[a]**




CCR: chemotherapy-containing regimen; CI: confidence interval; ER: emergency room; IP: inpatient; mCSPC: metastatic castration sensitive prostate cancer; NCR: non-chemotherapy containing regimen; OP: outpatient; PC: prostate cancer; PPPM: per-patient-per-month; US: United States.
*p-value < 0.05
**Notes:** a. Costs were inflated to 2023 US dollars using the medical care component of the consumer price index and were reported PPPM. b. The weighted model adjusted for the following baseline variables: all-cause pharmacy costs, categorical age (≤70, 71-80, ≥81), time between metastasis and index date, baseline time spent managing mCSPC, erectile dysfunction, nodal metastasis and Quan-Charlson comorbidity index score.

## Limitations

- Miscoding or misclassification in the clinical record or through the administrative claims may introduce selection and information biases despite efforts to balance the study populations
- Regression analyses could only adjust for measured covariates and residual confounding may be present

**References**
1. Lavole JM, et al. *Prostate*. 2019;79(3):281-287. 2. Cattrini C, et al. *Cancers (Basel)*. 2019;11(9):1355. 3. Eule CJ, et al. *Urol Oncol*. 2024;42(12):447.e417-447.e424. 4. Hussain M, et al. *J Clin Oncol*. 2023;41(20):3595-3607. 5. National Cancer Institute. Abiraterone Approved for Earlier Use in Men with Metastatic Prostate Cancer. 2018; https://www.cancer.gov/news-events/cancer-currents-blog/2018/abiraterone-fda-prostate-hormone-sensitive. 6. U.S. Food and Drug Administration. FDA approves darolutamide tablets for metastatic hormone-sensitive prostate cancer. 2022; https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-darolutamide-tablets-metastatic-hormone-sensitive-prostate-cancer. 7. Li F, et al. *Am J Epidemiol*. 2019;188(1):250-257. 8. Thomas LE, et al. *JAMA*. 2020;323(23):2417-2418. 9. Austin PC. *Stat Med*. 2009;28(25):3083-3107.

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