

# Real-world comparison of overall survival in patients with metastatic castration-sensitive prostate cancer initiating apalutamide without docetaxel versus darolutamide without docetaxel

Benjamin Lowentritt<sup>1</sup>, Mehmet A. Bilen<sup>2</sup>, Mukul Singhal<sup>3</sup>, Carmine Rossi<sup>4</sup>,  
Dominic Pilon<sup>4</sup>, Courtney D. Morrow<sup>3</sup>, Gordon Brown<sup>5</sup>

<https://www.jnjmedicalconnect.com/media/attestation/congresses/oncology/2026/ipcu/real-world-comparison-of-overall-survival-in-patients-with-metastatic-castration-presentation.pdf>

<https://www.jnjmedicalconnect.com/media/attestation/congresses/oncology/2026/ipcu/real-world-comparison-of-overall-survival-in-patients-with-metastatic-castration-pls.pdf>



Scan the QR code  
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.

<sup>1</sup> Chesapeake Urology, Towson, MD

<sup>2</sup> Winship Cancer Institute of Emory University, Atlanta, GA

<sup>3</sup> Johnson & Johnson, Horsham, PA, USA

<sup>4</sup> Analysis Group, Inc., Montréal, Canada

<sup>5</sup> New Jersey Urology, Cherry Hill, NJ

# Background

✓ Apalutamide and darolutamide are approved for use in mCSPC<sup>1,2</sup>

📋 Phase 3 trials

## TITAN<sup>3</sup> (apalutamide + ADT)

↓ Significant reduction in disease progression

↓ Significant reduction in OS

## ARANOTE<sup>4</sup> (darolutamide + ADT)

↓ Significant reduction in disease progression

⚠️ No significant reduction in OS

✗ No clinical trials or real-world studies **directly comparing survival outcomes** between APA and DARO



Real world study comparing the **proportion of patients surviving by 24 months**

In patients with mCSPC who newly initiated:

Apalutamide without docetaxel

VS

Darolutamide without docetaxel

APA, apalutamide; ARPI, androgen receptor pathway inhibitor; DARO, darolutamide; mCSPC, metastatic castration-sensitive prostate cancer; OS, overall survival.

1. U.S. Food and Drug Administration. FDA approves apalutamide for metastatic castration-sensitive prostate cancer. 2019. Available at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-apalutamide-metastatic-castration-sensitive-prostate-cancer>. Accessed 18 Dec 2025; 2. U.S. Food and Drug Administration. FDA approves darolutamide for metastatic castration-sensitive prostate cancer. 2025. Available at: <https://www.fda.gov/drugs/resources-information-approved-drugs/fda-approves-darolutamide-metastatic-castration-sensitive-prostate-cancer>. Accessed 18 Dec 2025; 3. Chi KN, et al. N Engl J Med. 2019;381(1):13–24; 4. Saad F, et al. J Clin Oncol. 2024;42(36):4271–4281;

# Methods

Retrospective longitudinal analysis using intention-to-treat approach comparing overall survival in ARPI-naïve patients with mCSPC newly initiated on apalutamide without docetaxel versus darolutamide without docetaxel

## Primary endpoint



Overall survival by 24 months



**Precision Point Specialty**  
A clinical EMR database



**Data sources**  
Linking patient level data



**Komodo Research Database**  
An insurance claims database with mortality



**Study period:** 01/01/2016 – 06/30/2025

Precision Point Specialty Analytics Database  
linked to Komodo Research Claims Database

≥1 paid claim or dispensation for any ARPI on or after  
August 5, 2022 (first paid claim or dispensation = index date)  
N=19,338

Apalutamide as first  
paid claim or dispensation  
N=3,239

Darolutamide as first  
paid claim or dispensation  
N=1,815

Patient selection criteria met

**Apalutamide cohort**  
N=1,460

**Darolutamide cohort**  
N=287

## Statistical analyses

Power calculation

Adequately  
powered

Balance confounding  
baseline variables

IPTW

Compare OS  
between cohorts

Weighted Cox  
proportional  
hazards model



### Select Inclusion criteria

- Adult patients with ARPI-naïve mCSPC



### Select Exclusion criteria

- Evidence of docetaxel use within -90/+30 days & -/+90 days of index date (SA)
- Prior use of an ARPI or advanced treatment
- Diagnosis for another primary cancer

ARPI, androgen receptor pathway inhibitor; EMR, electronic medical records; IPTW, inverse-probability of treatment weighting; mCSPC, metastatic castration-sensitive prostate cancer; OS, overall survival; SA, Sensitivity analyses.

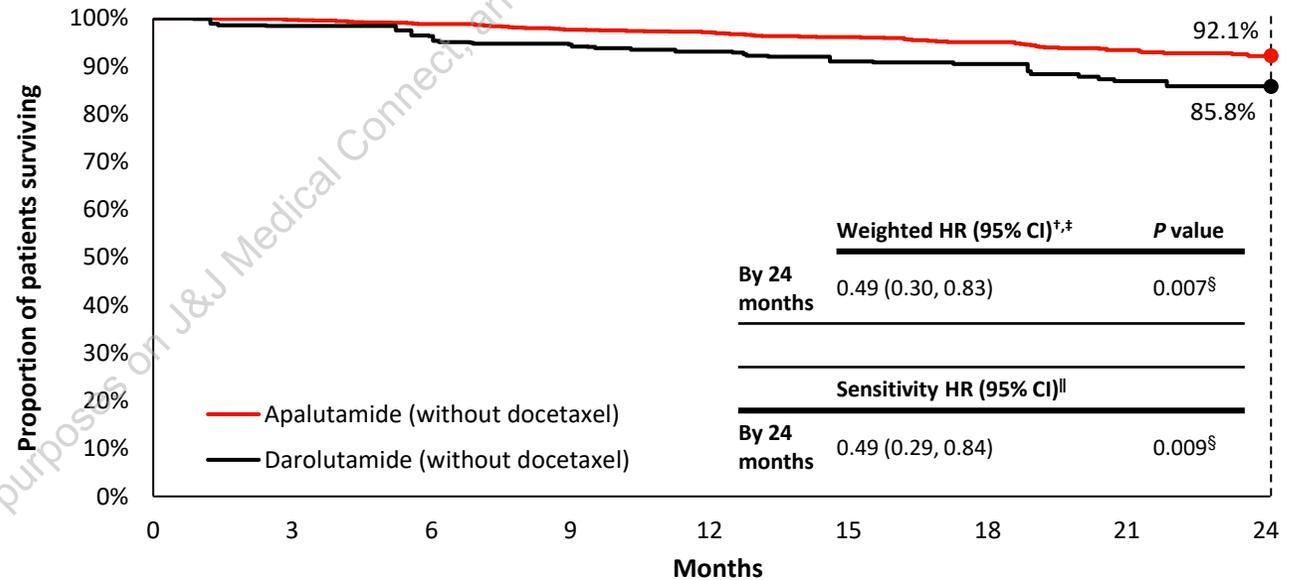
# Results

## Patient population

Select patient characteristics*	Apalutamide (without docetaxel) N=1,460	Darolutamide (without docetaxel) N=287	Standardized difference, %
Mean age, years	73.5	73.7	2.6
<b>Race</b>			
White	59.6%	60.0%	0.8
Black	21.5%	22.4%	2.4
Other	13.5%	12.4%	3.4
Unknown	5.4%	5.2%	1.2
Medicare-insured	79.8%	81.4%	4.1
<b>Index year</b>			
2022	11.9%	11.8%	0.3
2023	39.1%	39.0%	0.3
2024	36.8%	37.3%	1.0
2025	12.1%	11.9%	0.7
Median (IQR time between metastasis and index date, months)	4.1 (1.1, 17.1)	2.9 (1.0, 16.3)	3.4
Mean Quan-CCI	10.1	10.0	2.9
<b>Metastasis type</b>			
Bone	53.6%	52.9%	1.4
Nodal	50.1%	47.8%	4.6
Visceral	17.6%	18.5%	2.1
Multiple sites	28.4%	29.0%	1.2
De novo mCSPC	39.1%	37.0%	4.3
Concurrent use of ADT	96.4%	95.6%	3.9
Most recent ADT episode index date ≤4 months	67.0%	70.5%	7.6

## Overall survival

Through 24 months: Apalutamide demonstrated **↓ 51%** reduction in risk of death



	12 months	24 months
Apalutamide (without docetaxel)	961 (65.8%)	456 (31.2%)
Darolutamide (without docetaxel)	201 (69.9%)	87 (30.3%)

\*After inverse probability of treatment weighting. <sup>†</sup>Propensity scores were generated using probability estimates from a logistic regression models using the following predictors: age, race, geographic region, payer, year of index date, time between metastasis and index date, time between first observed PC diagnosis and index date, de novo mCSPC, concurrent use of ADT, prior use of first-generation antiandrogens, bone antiresorptive therapy, most recent PSA level, earliest Gleason score, types of metastases (bone, nodal, visceral, and metastasis in multiple sites), and Quan-CCI score. Each patient was attributed an inverse-probability of treatment weight that was defined as follows: 1/(propensity score) for the apalutamide cohort and 1/(1-propensity score) for the darolutamide cohort. Normalized inverse-probability of treatment weights were truncated at the 95th percentiles. <sup>‡</sup>A hazard ratio <1 indicates that the apalutamide cohort has a lower likelihood of death compared to the darolutamide cohort. <sup>§</sup>Significant at the 5% level. <sup>||</sup>Excluded patients with docetaxel use between 90 days pre-index to 90 days post-index.

ADT, androgen deprivation therapy; CI, confidence interval; HR, hazard ratio; IQR, interquartile range; mCSPC, metastatic castration-sensitive prostate cancer; PSA, prostate specific antigen; Quan-CCI, Quan-Charlson Comorbidity Index.

# Limitations and conclusions

## Limitations

1. Potential for misclassification bias
2. Possibility that not all death or treatment data captured
3. Unknown cofounders may be present
4. Longer follow-up may be required

APA, apalutamide; mCSPC, metastatic castration-sensitive prostate cancer; OS, overall survival.

1. Chi KN, et al. *J Clin Oncol.* 2021;39(20):2294-2303.G;2. Bilen, Mehmet A., et al. *Advances in Therapy* (2025): 1-18.; 3. Lowentritt, Benjamin, et al. *Urologic Oncology.* Vol. 41. No. 5. Elsevier, 2023.

## Conclusions



In mCSPC patients:

Apalutamide without docetaxel

**51%**

reduction in the risk of death  
using 24-month follow-up data  
vs

Darolutamide without docetaxel

Comparison with previous studies:

**Consistent** in sensitivity analyses with larger docetaxel exclusion window

APA 24-month OS **consistent with** Phase 3 TITAN<sup>1</sup> and previously published RW studies<sup>2,3</sup>



# Questions?

This material is distributed for scientific purposes on J&J Medical Connect, and is not for promotional use

<https://www.jnjmedicalconnect.com/media/attestation/congresses/oncology/2026/ipcu/real-world-comparison-of-overall-survival-in-patients-with-metastatic-castration-presentation.pdf>

<https://www.jnjmedicalconnect.com/media/attestation/congresses/oncology/2026/ipcu/real-world-comparison-of-overall-survival-in-patients-with-metastatic-castration-pls.pdf>



Scan the QR code  
The QR code is intended to provide scientific information for individual reference, and the information should not be altered or reproduced in any way.