

Overall Survival with Apalutamide vs Enzalutamide in Metastatic Castration-Sensitive Prostate Cancer

Mehmet A. Bilen, MD^a, Benjamin Lowentritt, MD^b, Ibrahim Khilfeh, PharmD^c, Carmine Rossi, PhD^d, Shawn Du, PhD^c, Frederic Kinkead, MA^d, Lilian Diaz, MSc^d, Dominic Pilon, MSc^d, Lorie Ellis, PhD^c, Neal D. Shore, MD, FACS^e

^a Winship Cancer Institute of Emory University, Atlanta, Georgia, USA

^b Chesapeake Urology, Towson, Maryland, USA

^c Johnson & Johnson, Horsham, Pennsylvania, USA

^d Analysis Group, Inc., Montréal, Québec, Canada

^e Carolina Urologic Research Center, Myrtle Beach, South Carolina, USA

Corresponding author:

Neal Shore, MD, FACS

Carolina Urologic Research Center

823 82nd Parkway

Myrtle Beach, South Carolina 29572

Phone: +1-843-839-1679

Fax: +1-843-497-6171

Email: nshore@auclinics.com

Supplementary Table 1. Castration-resistance algorithm

Assessment of castration resistance will be based on a previously published algorithm incorporating presence of ADT and PSA levels.¹ All patients with evidence of castration resistance prior to or on the index date were excluded from this study. Castration resistance was defined using one of the following four criteria with the earliest observed date for any of these criteria defined as the initial castration resistance date:

Castration resistance criteria	Description
≥ 1 indicator for CRPC based on provided variables in PPS	The indicator considered one of the following criteria: two consecutive rises in PSA while on continuous luteinizing hormone-releasing hormone therapy for more than six months, the presence of enzalutamide before it received a non-CRPC indication, manual data entry by a clinical user, the presence of the Z19.2 ICD-10-CM diagnosis code, and parsable encounter notes in the EMR where a physician indicated that patients progressed to CRPC. If a patient was considered by at least one of these criteria as castration-resistant, then the patient was identified as castration-resistant.
≥ 1 diagnosis for castration resistant malignancy status	≥ 1 claim with a diagnosis code ICD-10-CM: Z19.2 identified in PPS or KRD
Surgical castration and ≥ 1 rise in PSA from post-castration nadir	≥ 1 record for bilateral orchiectomy observed at any time before the first observed ARPI used AND ≥ 2 PSA test results at any time before the first observed ARPI used (including one nadir and one post-nadir) after the procedure, with ≥ 1 rise in PSA (of $\geq 25\%$ with an absolute increase of ≥ 2 ng/mL) after nadir. Nadir was defined as the lowest PSA value observed between the procedures and the first ARPI claim.
Medical castration and ≥ 1 rise in PSA from post-castration nadir	≥ 90 days of continuous ADT use observed at any time before the first observed ARPI use AND ≥ 2 PSA test results at any time before the first observed ARPI used (including one nadir and one post-nadir) within the same episode of continuous ADT, with ≥ 1 rise in PSA (of $\geq 25\%$ with an absolute increase of ≥ 2 ng/mL) after nadir. Nadir was

	defined as the lowest PSA value observed between the procedures and the first ARPI claim.
--	---

ADT: androgen deprivation therapy; ARPI: androgen receptor pathway inhibitor; CRPC: castration-resistant prostate cancer; ICD-10-CM: International Classification of Diseases, 10th Revision, Clinical Modification; PSA: prostate-specific antigen.

Reference:

[1] Freedland SJ, Ke X, Lafeuille MH, et al. Identification of patients with metastatic castration-sensitive or metastatic castration-resistant prostate cancer using administrative health claims and laboratory data. *Curr Med Res Opin.* Apr 2021;37(4):609-622.
doi:10.1080/03007995.2021.1879753