

Clinical Policy Title:	enzalutamide
Policy Number:	RxA.318
Drug(s) Applied:	Xtandi®
Original Policy Date:	02/07/2020
Last Review Date:	12/11/2025
Line of Business Policy Applies to:	All lines of Business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of one of the following (a, b, or c):
 - a. Castration-resistant prostate cancer (CRPC);
 - b. Metastatic castration-sensitive prostate cancer;
 - c. Non-metastatic castration-sensitive prostate cancer with biochemical recurrence at high risk for metastasis.
2. For diagnoses of CRPC and metastatic castration-sensitive prostate cancer, member meets one of the following (a or b):
 - a. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog;
 - b. Patient has had a bilateral orchiectomy.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Prostate Cancer Version 01.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed March 21, 2025.
2. Virgo KS, Basch E, Loblaw DA, et al. Second-Line Hormonal Therapy for Men with Chemotherapy-Naïve Castration-Resistant Prostate Cancer. American Society of Clinical Oncology (ASCO). Published online April 25, 2017, DOI: 10.1200/JCO.2017.72.8030. Available at: <https://www.asco.org/practice-patients/guidelines/genitourinary-cancer#/25251>. Accessed March 21, 2025.
3. Virgo KS, Rumble B, de Wit R, et al. Initial Management of Non-Castrate Advanced, Recurrent or Metastatic Prostate Cancer. American Society of Clinical Oncology (ASCO). Published ahead of print January 26, 2021. DOI: 10.1200/JCO.20.03256. Available at: <https://www.asco.org/practice-patients/guidelines/genitourinary-cancer#/9521>. Accessed March 21, 2025.

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

4. Basch E, Loblaw DA, Oliver TK, et al. Systemic Therapy in Men with Metastatic Castration-Resistant Prostate Cancer (CRPC). American Society of Clinical Oncology (ASCO). Published August 15, 2022. Available at: <https://www.asco.org/practice-patients/guidelines/genitourinary-cancer#/9496>. Accessed March 21, 2025.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established	01/2020	02/07/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Initial Approval criteria updated to include criteria for metastatic castration-sensitive prostate cancer(mCSPC). 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Initial and continued approval duration for Medicaid was added; commercial approval duration was updated to 6 months. 6. References were updated.	07/24/2020	09/14/2020
Policy was reviewed: 1. References were reviewed and revised. 2. Updated off-label dosing criteria under I.A.5 and II.A.3.	04/15/2021	06/10/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated to include new hormone therapy criteria As secondary hormone therapy^ for M0 castration-resistant disease and PSA doubling time (PSADT) ≤ 10 months. 2. Initial Approval Criteria, I.A.6: Updated to include new hormone therapy criteria As secondary hormone therapy^ for castration-resistant distant metastatic (M1) disease, and if received no prior docetaxel and no prior novel hormone therapy.	01/28/2022	04/18/2022

3. References were reviewed and updated.		
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.5: Updated to remove as secondary hormone therapy * for M0 castration-resistant disease and PSA doubling time (PSADT) ≤ 10 months. 2. Initial Approval Therapy I.A.6: Updated to remove as secondary hormone therapy * for castration-resistant distant metastatic (M1) disease, and if received no prior docetaxel and no prior novel hormone therapy. 3. Initial and Continued therapy Criteria: Verbiage indicating number of capsules (e.g. 2 capsules per day) removed from dose does not exceed criteria. 4. References were reviewed and updated. 	01/10/2023	04/13/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed requirement for evidence of disease progression despite bilateral orchiectomy or other androgen deprivation therapy from diagnosis. 2. Removed prior age criteria. 3. Removed prior dosing criteria. 4. Updated approval duration. 5. Removed reauthorization requirement for positive response to therapy. 6. References were reviewed and updated. 	12/12/2023	01/01/2024
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescriber criteria. 2. Updated continuation of therapy language. 3. References were reviewed and updated. 	12/12/2023	01/01/2024
Policy was reviewed:	12/11/2025	12/11/2025

