Clinical Policy Title:	enzalutamide
Policy Number:	RxA.318
Drug(s) Applied:	Xtandi®
Original Policy Date:	02/07/2020
Last Review Date:	01/01/2024
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 Castration-Resistant Prostate Cancer (CRPC) or Metastatic Castration-Sensitive Prostate Cancer (mCSPC) .
2. Member meets one of the following (a or b):
   a. Receiving gonadotropin-releasing hormone (GnRH) analog
   b. Patient has had a bilateral orchiectomy;
3. Prescribed by or in consultation with an oncologist or urologist;

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all)**:**

1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Prostate Cancer Version 01.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed December 12, 2023.
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 December 12, 2023.
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 December 12, 2023.
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 December 12, 2023.

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. 3. References were reviewed and updated.	01/28/2022	04/18/2022
Policy was reviewed: 1. Initial Approval Criteria I.A.5:	01/10/2023	04/13/2023

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.		
Policy was reviewed: 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