VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Xtandi Prior Authorization Policy
- Xtandi® (enzalutamide capsules and tablets – Astellas/Pfizer)

REVIEW DATE: 04/05/2023; selected revision 11/29/2023

OVERVIEW

Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with **castration-resistant prostate cancer (CRPC), metastatic castration-sensitive prostate cancer (mCSPC)**, and **non-metastatic castration-sensitive prostate cancer (nmCSPC)** with biochemical recurrence at high risk for metastasis (high-risk biochemical recurrence [high-risk BCR]).[1] For CRPC and mCSPC, patients should receive Xtandi with a concurrent gonadotropin-releasing hormone (GnRH) analog or should have had a bilateral orchiectomy. Patients with nmCSPC with high-risk BCR may be treated with or without a GnRH analog.

Guidelines

According to the National Comprehensive Cancer Network (NCCN) guidelines on prostate cancer (version 1.2023 – September 16, 2022), all patients with metastatic CRPC should continue androgen deprivation therapy to maintain castrate levels of serum testosterone (< 50 ng/dL).

- For patients with non-metastatic CRPC, if the prostate specific antigen doubling time is ≤ 10 months, Xtandi, Erleada® (apalutamide tablets), and Nubeqa® (darolutamide tablets) are all preferred category 1 recommended options.
- For patients with mCRPC adenocarcinoma, therapies are based on prior docetaxel or prior novel hormone therapy use.
    - No prior docetaxel and no prior novel hormone therapy: the preferred regimens are Xtandi (category 1), abiraterone (category 1 only if no visceral metastases), and docetaxel (category 1).
    - Prior docetaxel, but no prior novel hormone therapy: the preferred regimens include Xtandi or abiraterone (both category 1), and Jevtana® (cabazitaxel intravenous infusion) [category 2A].
    - Prior novel hormone therapy but no prior docetaxel: Xtandi, abiraterone, and abiraterone + dexamethasone are "other recommended regimens" (both category 2A).
    - Prior docetaxel and prior novel hormone therapy: All systemic therapies are category 2B if visceral metastases are present. Preferred regimens are Jevtana (category 1) and docetaxel rechallenge. Xtandi, abiraterone, and other secondary hormone therapy are "other recommended regimens" (all category 2A).
- For mCSPC androgen deprivation therapy in combination with Xtandi, abiraterone + steroid, Erleada, and docetaxel are all category 1 recommended preferred options. Yonsa® (abiraterone acetate) with methylprednisolone is a category 2B recommendation.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Xtandi. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Xtandi is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Prostate Cancer – Castration-Resistant (Metastatic or Non-Metastatic).** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist; OR
       Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
     - **ii.** The medication is concurrently used with Firmagon (degarelix subcutaneous injection); OR
     - **iii.** Patient has had a bilateral orchiectomy.

2. **Prostate Cancer – Metastatic, Castration-Sensitive.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i, ii, or iii):
     - **i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist; OR
       Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
     - **ii.** The medication is concurrently used with Firmagon (degarelix subcutaneous injection); OR
     - **iii.** Patient has had a bilateral orchiectomy.

3. **Prostate Cancer – Non-Metastatic, Castration-Sensitive.** Approve for 1 year if the patient meets the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has biochemical recurrence and is at high risk for metastasis.
     Note: High-risk biochemical recurrence is defined as prostate-specific antigen (PSA) doubling time ≤ 9 months.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Xtandi is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Xtandi® capsules and tablets [prescribing information]. Northbrook, IL: Astellas/Pfizer; November 2023.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 2, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Prostate Cancer – Castration-Resistant (Metastatic or Non-Metastatic).** A requirement was added that the patient is ≥ 18 years of age. The criterion requiring trial of gonadotropin-releasing hormone "analog" was revised to "agonist". A requirement that the medication is used in combination with Firmagon (degarelix subcutaneous injection) was added. **Prostate Cancer – Metastatic, Castration-Sensitive:** A requirement was added that the patient is ≥ 18 years of age. The criterion requiring trial of gonadotropin-releasing hormone "analog" was revised to "agonist". A requirement that the medication is used in combination with Firmagon (degarelix subcutaneous injection) was added.	04/06/2022
Selected Revision	**Prostate Cancer – Castration-Resistant (Metastatic or Non-Metastatic).** The duration of approval was changed from 3 years to 1 year. **Prostate Cancer – Metastatic, Castration-Sensitive:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Annual Revision	No criteria changes	04/05/2023
Selected Revision	**Prostate Cancer – Non-Metastatic, Castration-Sensitive.** Added new condition and criteria based on new indication approval.	11/29/2023