PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/10/2024

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 3.2024 – March 8, 2024), 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). Talzenna® (talazoparib capsules) + Xtandi is recommended for homologous recombination repair (HRR) mutation (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]. Talzenna + Xtandi for HRR mutation is a category 2A recommendation.
    - Prior novel hormone therapy but no prior docetaxel: Xtandi, abiraterone, and abiraterone + dexamethasone are "other recommended regimens" (both category 2A). Talzenna + Xtandi for HRR mutation is a category 2B recommendation in this setting.
    - 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 progressive non-metastatic CSPC after maximal pelvic therapy, Xtandi ± leuprolide is recommended as "useful in certain circumstances" (category 2A). It is recommended in patients who have the following high-risk criteria: non-metastatic by conventional imaging; prostate-specific antigen (PSA) doubling time (PSADT) ≤ 9 month; PSA ≥ 2 ng/mL above nadir after radiotherapy or ≥ 1 ng/mL after radiotherapy with or without postoperative radiotherapy; and not considered a candidate for pelvic-directed therapy.
- 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 or ii):
     - **i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
       Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
     - **ii.** 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 or ii):
     - **i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
       Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).
     - **ii.** 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 3.2024 – March 8, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 8, 2024.