PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 03/17/2021

OVERVIEW

Xtandi is an androgen receptor inhibitor indicated for the treatment of patients with **castration-resistant prostate cancer (CRPC)** and **metastatic castration-sensitive prostate cancer (mCSPC)**.[1] Patients should receive Xtandi with a concurrent gonadotropin-releasing hormone (GnRH) analog or should have had a bilateral orchiectomy.

Guidelines

According to the NCCN guidelines on prostate cancer (version 2.2021 – February 17, 2021), all patients with mCRPC should maintain castrate levels of serum testosterone (< 50 ng/dL) and receive best supportive care.[2] Erleada™ (apalutamide tablets), Nubeqa (darolutamide tablets), and Xtandi are all category 1 recommended options for non-metastatic CRPC (M0) especially if the prostate specific antigen doubling time (PSADT) ≤ 10 months.

- For patients who progress to CRPC and are positive for distant metastasis, M1, and there are no visceral metastases, Zytiga® (abiraterone acetate tablets) and prednisone, docetaxel, Xtandi, and Xofigo® (radium Ra 223 dichloride injection, for intravenous use) [for symptomatic bone metastases] are all category 1 recommended options.
  - If there are visceral metastases, and if it is adenocarcinoma (majority), the guidelines categorize therapies based on prior docetaxel or prior novel hormone therapy use. Novel hormone therapies include abiraterone, Xtandi, Nubeqa, or Erleada received for mestastic castration-naïve disease, non-metastatic CRPC, or previous line of therapy for metastatic CRPC.
    - 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, abiraterone (both category 1), and Jevtana (cabazitaxel for intravenous use).
    - Prior novel hormone therapy but no prior docetaxel: Xtandi, abiraterone 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, Zytiga, and other secondary hormone therapy are "other recommended regimens" (all category 2A).
  - For metastatic, castration-naïve disease, ADT in combination with abiraterone + prednisone, Erleada, docetaxel, and Xtandi are all category 1 recommended 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 3 years in duration unless otherwise noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Prostate Cancer –Castration-Resistant (CRPC) [Metastatic or Non-Metastatic].** Approve for 3 years if the patient meets the following criteria (A or B):
   - **A)** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog.
     Note: Examples are Lupron (leuprolide for injection), Lupron Depot (leuprolide acetate for depot suspension), Trelstar (triptorelin pamoate for injectable suspension), Zoladex (goserelin acetate implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix for injection); OR
   - **B)** Patient has had a bilateral orchiectomy.

2. **Prostate Cancer – Metastatic, Castration-Sensitive.** Approve for 3 years if the patient meets one of the following criteria (A or B):
   - **A)** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog.
     Note: Examples are Lupron (leuprolide for injection), Lupron Depot (leuprolide acetate for depot suspension), Trelstar (triptorelin pamoate for injectable suspension), Zoladex (goserelin acetate implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix for injection); OR
   - **B)** Patient has had a bilateral orchiectomy.

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® [prescribing information]. Northbrook, IL: Astellas Pharma US, Inc.; August 2020.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 2.2021 – February 17, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed March 15, 2021.