VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Erleada Prior Authorization Policy
- Erleada® (apalutamide tablets – Janssen Pharmaceuticals)

REVIEW DATE: 03/17/2021

OVERVIEW

Erleada is indicated for the treatment of patients with **non-metastatic, castration-resistant prostate cancer (nmCRPC)** and **metastatic castration-sensitive prostate cancer (CSPC)**.[1] Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or the patient should have had a bilateral orchiectomy.

GUIDELINES

According to the National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer, (version 2.2021 – February 17, 2021) for nmCRPC, androgen deprivation therapy (ADT) is continued to maintain castrate serum levels of testosterone (< 50 ng/dL).[2] Erleada, Xtandi® (enzalutamide capsules), and Nubeqa® (darolutamide tablets) are all category 1 recommended options especially if the PSADT is ≤ 10 months. Other secondary hormone therapy is recommended if PSADT is ≤ 10 months (category 2A): for non-metastatic (M0) CRPC, the options are nilutamide, flutamide, bicalutamide, ketoconazole, corticosteroids. For metastatic, castration-naïve disease, ADT in combination with abirateron + prednisone, Erleada, 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 Erleada. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indications

1. **Prostate Cancer – Non-Metastatic, Castration-Resistant.** Approve Erleada for 3 years if the patient meets one of the following criteria (A or B):
   - **A)** The medication is used in combination with a gonadotropin-releasing hormone (GnRH) analog. Note: Examples are Lupron (leuprolide acetate 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 in combination with a gonadotropin-releasing hormone (GnRH) analog. Note: Examples are Lupron (leuprolide acetate 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 Erleada 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. Erleada™ [prescribing information]. Horsham, PA: Janssen Pharmaceutical Companies; November 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 14, 2021.