VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Erleada (apalutamide tablets – Janssen Pharmaceuticals)

TAC APPROVAL DATE: 02/27/2019; 09/25/2019 selected revision

OVERVIEW

Erleada is indicated for the treatment of patients with non-metastatic, castration-resistant prostate cancer (nmCRPC).[1] It is also indicated in patients with metastatic castration-sensitive prostate cancer (CSPC). Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or the patient should have had a bilateral orchiectomy. Erleada is an androgen receptor inhibitor that binds directly to the ligand-binding domain of the androgen receptor.

GUIDELINES

According to the National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer, (version 4.2019 – August 19, 2019) 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) agonist 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); OR
   - **B)** The 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) agonist 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); OR

B) The patient has had a bilateral orchiectomy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Erleada has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval.)

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; September 2019.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 4.2019 – August 19, 2019). © 2019 National Comprehensive Cancer Network Inc. Available at: http://www.nccn.org. Accessed August 19, 2019.

HISTORY

Type of Revision	Summary of Changes*	TAC Approval Date
New Policy	New criteria	02/16/2018
Annual revision	No criteria changes	02/27/2019
Selected revision	Added new FDA-approved indication for metastatic castration-sensitive prostate cancer. Also added criteria for both indications that the medication is used in combination with gonadotropin-releasing hormone agonist or patient has had an orchiectomy.	09/25/2019

* For a further summary of criteria changes, refer to respective TAC minutes available at: http://esidepartments/sites/Dep043/Committees/TAC/Forms/AllItems.aspx; TAC – Therapeutic Assessment Committe.