

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Erleada Prior Authorization Policy

- Erleada® (apalutamide tablets – Janssen)

REVIEW DATE: 04/10/2024

OVERVIEW

Erleada, an androgen receptor inhibitor, is indicated for the treatment of patients with **non-metastatic, castration-resistant prostate cancer (nmCRPC)** and **metastatic castration-sensitive prostate cancer (mCSPC)**.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 3.2024 – March 8, 2024)²:

- For nmCRPC, Erleada, Xtandi® (enzalutamide capsules or tablets), and Nubeqa® (darolutamide tablets) are all preferred category 1 recommended options, if the prostate specific antigen doubling time is ≤ 10 months.
- For mCSPC, androgen deprivation therapy in combination with abiraterone + steroid, Erleada, docetaxel, and Xtandi are all preferred category 1 recommended options. Yonsa® (abiraterone acetate tablets) 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 one of the following criteria:

FDA-Approved Indications

- 1. Prostate Cancer – Non-Metastatic, Castration-Resistant.** 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 in combination 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.

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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 in combination 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.

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® tablets [prescribing information]. Horsham, PA: Janssen; December 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.