PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 04/06/2022; selected revision 06/22/2022

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 (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 3.2022 – January 10, 2022):
- 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 criteria (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following criteria (i, ii, or iii):
     - **i.** The medication is used in combination with a gonadotropin-releasing hormone (GnRH) agonist; OR
       Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
     - **ii.** The medication is concurrently used with Firmagon (degarelix subcutaneous injection); OR
     - **iii.** Patient has had a bilateral orchiectomy.

2. **Prostate Cancer – Metastatic, Castration-Sensitive.** Approve for 1 year if the patient meets the following criteria (A and B):
   A) Patient is ≥ 18 years of age; AND
   B) Patient meets ONE of the following criteria (i, ii, or iii):
      i. The medication is used in combination with a gonadotropin-releasing hormone (GnRH) agonist; OR
      Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant)
      ii. The medication is concurrently used with Firmagon (degarelix subcutaneous injection); OR
      iii. 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; September 2021.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 3.2022 – January 10, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 4, 2022.