# PRIOR AUTHORIZATION POLICY

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

**REVIEW DATE:** 04/05/2023

***INSTRUCTIONS FOR USE***

*THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.*

## CIGNA NATIONAL FORMULARY COVERAGE:

## 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 1.2023 – September 16, 2022)[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.

- **Erleada® (apalutamide tablets ( Janssen)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

**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 COVERED**

- **Erleada® (apalutamide tablets ( Janssen)**

**is(are) considered experimental, investigational or unproven for ANY other use(s).**

## REFERENCES


1. Erleada® tablets [prescribing information]. Horsham, PA: Janssen; February 2023.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed April 2, 2023.


## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | **Prostate Cancer – Non-Metastatic, Castration-Resistant:** A requirement was added that the patient is ≥ 18 years of age. The criterion requiring trial of gonadotropin-releasing hormone "analog" was revised to "agonist". A requirement that the medication is used in combination with Firmagon (degarelix subcutaneous injection) was added.<br>**Prostate Cancer – Metastatic, Castration-Sensitive:** A requirement was added that the patient is ≥ 18 years of age. The criterion requiring trial of gonadotropin-releasing hormone "analog" was revised to "agonist". A requirement that the medication is used in combination with Firmagon (degarelix subcutaneous injection) was added. | 04/06/2022 |
| Selected Revision | **Prostate Cancer – Non-Metastatic, Castration-Resistant:** The duration of approval was changed from 3 years to 1 year.<br>**Prostate Cancer – Metastatic, Castration-Sensitive:** The duration of approval was changed from 3 years to 1 year. | 06/22/2022 |
| Annual Revision | No criteria changes | 04/05/2023 |