



**Prior Authorization  
Oncology – Erleada® (apalutamide tablets)**

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**INSTRUCTIONS FOR USE**

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**National Formulary Medical Necessity**

**Cigna covers apalutamide tablets (Erleada®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:**

Prior Authorization is recommended for prescription benefit coverage of Erleada. All approvals are provided for the duration noted below.

FDA Indication(s)

**Prostate Cancer – Non-Metastatic, Castration-Resistant.** Approve for 3 years 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 3 years 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

Apalutamide tablets (Erleada®) is considered experimental, investigational or unproven for ANY other use.

## Background

### 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)**.<sup>1</sup> 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.

## 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.

## Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	<p><b>Prostate Cancer – Non-Metastatic, Castration-Resistant:</b> 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.</p> <p><b>Prostate Cancer – Metastatic, Castration-Sensitive:</b> 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</p>	04/06/2022

	requirement that the medication is used in combination with Firmagon (degarelix subcutaneous injection) was added.	
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