

# Erleada (apalutamide)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

  

Medications	Quantity Limit
Erleada (apalutamide)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Erleada (apalutamide) may be approved if the following criteria are met:

- I. Individual is diagnosed with one of the following:
  - A. Individual has a diagnosis of non-metastatic castration-resistant\* prostate cancer (nmCRPC) (Label, NCCN 1); **AND**
  - B. Individual has a PSA doubling time (PSADT)  $\leq 10$  months;

**OR**

- C. Individual has a diagnosis of metastatic castration-sensitive prostate cancer (mCSPC)

**AND**

- II. One of the following:
  - A. Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron (leuprolide, Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix); **OR**
  - B. Individual has had a bilateral orchiectomy.

\*Castration-resistant refers to either surgical or medically induced methods. Medically induced methods include luteinizing hormone-releasing hormone (LHRH) agonists (such as leuprolide, goserelin) or LHRH antagonists (such as degarelix).

## **Key References:**

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2021. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: April 14, 2021.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2021; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 14, 2021.
  - a. Prostate Cancer. V2.2021. Revised February 17, 2021.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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