

# Nubeqa (darolutamide)

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

  

Medications	Quantity Limit
Nubeqa (darolutamide)	May be subject to quantity limit

## **APPROVAL CRITERIA**

Requests for Nubeqa (darolutamide) 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 hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel;

### **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. 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.: 2023. 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 13, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.

5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on April 13, 2023.
  - a. Prostate Cancer. V1.2023. Revised September 16, 2022.

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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