

# 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 (mCSPC) in combination with docetaxel (Label, NCCN 1); **OR**
  - D. Individual has a diagnosis of metastatic hormone-sensitive prostate cancer (mCSPC) (Label, NCCN 2A);

### **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. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: June 28, 2025.
2. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
3. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2025; Updated periodically.
4. NCCN Clinical Practice Guidelines in Oncology™. © 2025 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on June 28, 2025.
  - a. Prostate Cancer. V1.2025. Revised June 3, 2025.

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.

No part of this publication may be reproduced, stored in a retrieval system or transmitted, in any form or by any means, electronic, mechanical, photocopying, or otherwise, without permission from the health plan.