

Nubeqa[®] (darolutamide) (Oral)

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I. Length of Authorization

Coverage is provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Nubeqa 300 mg tablets: 4 tablets per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- 1200 mg daily

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria ¹

- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Will not be used in combination with other androgen receptor inhibitors (e.g., enzalutamide, apalutamide, etc.); **AND**
- Patient will avoid concomitant use with combined P-gp and strong or moderate CYP3A4 inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**
- Patient will avoid concomitant use with combined P-gp and strong CYP3A4 inhibitors (e.g., clarithromycin, fluvoxamine, ketoconazole, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will implemented; **AND**

Prostate Cancer † ^{1,2}

- Patient has NON-metastatic castration-resistant disease (nmCRPC); **OR**

- Patient has metastatic hormone-sensitive prostate cancer (mHSPC); **AND**
 - Used in combination with docetaxel
- † FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Ⓢ Orphan Drug

IV. Renewal Criteria ^{1,3}

Coverage can be renewed based upon the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: ischemic heart disease, seizures, etc.

V. Dosage/Administration ¹

Indication	Dose
Prostate Cancer	600 mg (two 300 mg tablets) taken orally, twice daily, until disease progression or unacceptable toxicity. <i>*Note: For patients with mHSPC treated with NUBEQA in combination with docetaxel, administer the first of 6 cycles of docetaxel within 6 weeks after the start of NUBEQA treatment. Refer to docetaxel prescribing information for additional dosing information, including dosage modifications.</i>

VI. Billing Code/Availability Information

HCPCS Code:

- J8999 – Prescription drug, oral, chemotherapeutic, Not Otherwise Specified
- C9399 – Unclassified drugs or biologicals (*for hospital outpatient use ONLY*)

NDC:

- Nubeqa 300 mg film-coated tablet: 50419-0395-xx

VII. References

1. Nubeqa [package insert]. Whippany, NJ; Bayer Pharmaceuticals; August 2022. Accessed August 2022
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium[®]) for darolutamide. National Comprehensive Cancer Network, 2022. The NCCN Compendium[®] is a derivative work of the NCCN Guidelines[®]. NATIONAL COMPREHENSIVE CANCER NETWORK[®], NCCN[®], and NCCN GUIDELINES[®] are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most

recent and complete version of the Compendium, go online to NCCN.org. Accessed August 2022.

3. Fizazi K, Shore N, Tammela TL, et al. Darolutamide in Nonmetastatic, Castration-Resistant Prostate Cancer. *N Engl J Med.* 2019 Mar 28;380(13):1235-1246. doi: 10.1056/NEJMoa1815671. Epub 2019 Feb 14.
4. Smith MR, Hussain M, Saad F, et al; ARASENS Trial Investigators. Darolutamide and Survival in Metastatic, Hormone-Sensitive Prostate Cancer. *N Engl J Med.* 2022 Mar 24;386(12):1132-1142. doi: 10.1056/NEJMoa2119115.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate
Z85.46	Personal history of malignant neoplasm of prostate

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC