

## Nubeqa™ (darolutamide) (Oral)

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### I. Length of Authorization

Coverage is provided for six months and may be renewed.

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Nubeqa 300 mg tablets: 4 tablets per day

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 1200 mg daily

### III. Initial Approval Criteria

Coverage is provided in the following conditions:

- Patient is at least 18 years old; **AND**
- Patient will receive 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 the following drugs:
  - Combined P-gp and Strong or Moderate CYP3A4 Inducer (e.g., rifampin, carbamazepine, St. John's Wort, etc); **OR**
  - Breast Cancer Resistance Protein (BCRP) Substrates (e.g., glyburide, statins, prazosin, etc); **AND**

#### Prostate Cancer †

- Patient has NON-metastatic castration-resistant disease (nmCRPC); **AND**
- Patient has a prostate-specific antigen (PSA) doubling time of  $\leq 10$  months; **AND**
- Patient has a baseline PSA  $> 2$  ng/mL

† FDA Approved Indication(s)

#### IV. Renewal Criteria

Coverage can be renewed based upon the following criteria:

- Patient continues to meet the criteria 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: any Grade 3 or higher toxicities or intolerable adverse reactions experienced by the patient, etc.

#### V. Dosage/Administration

Indication	Dose
Prostate Cancer	600 mg (two 300 mg film-coated tablets) taken orally, twice daily, equivalent to a total daily dose of 1200 mg. Swallow tablets whole with food <i>Note: Patients receiving Nubeqa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy.</i>

#### VI. Billing Code/Availability Information

Jcode:

- J8999- Prescription drug, oral, chemotherapeutic, Not Otherwise Specified

NDC:

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

#### VII. References

1. Nubeqa [package insert]. Whippany, NJ; Bayer Pharmaceuticals; July 2019. Accessed July 2019.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for darolutamide. National Comprehensive Cancer Network, 2019. 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 July 2019.

#### Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate

Z85.46	Personal history of malignant neoplasm of prostate
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## 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) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-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): 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