



Commercial/Healthcare Exchange PA Criteria

Effective: October 18th, 2019

Prior Authorization: Nubeqa

Products Affected: Nubeqa (darolutamide) oral tablets

Medication Description: Nubeqa (darolutamide) is androgen receptor (AR) inhibitor and competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. In vitro, darolutamide decreased prostate cancer cell proliferation and functioned as a progesterone receptor (PR) antagonist. The adverse reactions profile of darolutamide is thought to differ from other drugs in this class due to its distinct structure and characteristics that result in low penetration if the blood-brain barrier and low binding affinity for gamma-aminobutyric acid type A receptors in preclinical studies.

Covered Uses:

1. Treatment of patients with non-metastatic castration-resistant prostate cancer
2. Treatment of patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by or in consultation with an oncologist and/or urologist

Coverage Duration: 3 years

Other Criteria:

Nubeqa (darolutamide) may be considered medically necessary when all of the following selection criteria are met:

1. The patient has a diagnosis of non-metastatic castration-resistant prostate cancer; **OR**
2. The patient has a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel; **AND**
3. Patient meets one of the following criteria (a **or** b):
 - a. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog
Note: Examples are Lupron (leuprolide injection), Lupron Depot (leuprolide acetate depot suspension), Trelstar (triptorelin pamoate injectable suspension), Zoladex (goserelin acetate implant), Firmagon (degarelix injection), Vantas (histrelin acetate subcutaneous implant). **OR**
 - b. Patient has had a bilateral orchiectomy.

References:

1. Nubeqa® [prescribing information]. Whippany, NJ: Bayer; January 2021.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2022 – September 10, 2021). © 2021 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed September 20, 2021.

Last Rev.Sept 2022



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Policy Revision history:

Rev #	Type of Change	Summary of Change	Sections Affected	Date
3	Policy Update	Added new indication: metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel	Other Criteria	9/29/2022
2	Policy Update	Added “The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog OR Patient has had a bilateral orchiectomy” to other criteria Added urologist to prescriber restrictions	Prescriber Restrictions Other Criteria	7/26/2022
1	New Policy	New Policy	All	10/07/2019

