



**Prior Authorization
Oncology – Nubeqa® (darolutamide tablets)**

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INSTRUCTIONS FOR USE

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National Formulary Medical Necessity

Cigna covers darolutamide (Nubeqa®) as medically necessary when the following criteria are met for FDA Indications or Other Uses with Supportive Evidence:

Prior authorization is recommended for prescription benefit coverage of Nubeqa. All approvals are provided for the duration noted below.

FDA Indication(s)

- 1. Prostate Cancer – Metastatic, Castration-Sensitive.** Approve for 1 year if the individual meets the following criteria (A, B, and C):
 - A)** Individual is ≥ 18 years of age; AND
 - B)** The medication is used concurrently with docetaxel; AND
 - C)** Individual meets ONE of the following criteria (i, ii, or iii):
 - i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist; OR

Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).

- ii. The medication is used concurrently with Firmagon (degarelix subcutaneous injection); OR
- iii. Individual has had a bilateral orchiectomy.

2. Prostate Cancer – Non-Metastatic, Castration-Resistant. Approve for 1 year if the individual meets the following criteria (A and B):

A) Individual is ≥ 18 years of age; AND

B) Individual meets one of the following criteria (i, ii, or iii):

- i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) agonist; OR
Note: Examples of GnRH agonists include: leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant).
- ii. The medication is used concurrently with Firmagon (degarelix subcutaneous injection); OR
- iii. Individual has had a bilateral orchiectomy.

Conditions Not Covered

Darolutamide (Nubeqa®) is considered experimental, investigational or unproven for ANY other use.

Background

Overview

Nubeqa, an androgen receptor inhibitor, is indicated for the treatment of adults for the following uses:¹

- **Prostate cancer, metastatic, hormone-sensitive**, in combination with docetaxel.
- **Prostate cancer, non-metastatic, castration-resistant**.

Guidelines

According to the National Comprehensive Cancer Network guidelines for **prostate cancer** (version 4.2022 – May 10, 2022), for non-metastatic, castration-resistant prostate cancer, androgen deprivation therapy is continued to maintain castrate serum levels of testosterone (< 50 ng/dL).² Nubeqa, Erleada™ (apalutamide tablets) and Xtandi® (enzalutamide capsules) are all category 1 preferred regimens if the prostate specific antigen doubling time is ≤ 10 months. For metastatic castration naïve prostate cancer, the guidelines recommend abiraterone, Xtandi, Erleada, and docetaxel as preferred agents (category 1).

References

1. Nubeqa® tablets [prescribing information]. Whippany, NJ: Bayer; August 2022.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – May 10, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed August 8, 2022.

Revision History

Type of Revision	Summary of Changes	Approval Date
Annual Revision	Prostate Cancer – Non-Metastatic, Castration-Resistant: A requirement was added that the patient is ≥ 18 years of age.	09/22/2021
Selected Revision	Prostate Cancer – Non-Metastatic, Castration-Resistant: The duration of approval was changed from 3 years to 1 year.	06/22/2022
Early Annual Revision	Prostate Cancer – Metastatic, Castration-Sensitive: Indication and criteria were added due to FDA approval for this indication. Prostate Cancer – Non-Metastatic, Castration-Resistant: The criterion requiring trial of gonadotropin-releasing hormone “analog” was revised to	08/10/2022

	"agonist". Criterion was added for concurrent use with Firmagon (degarelix subcutaneous injection).	
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