VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology (Oral – Androgen Receptor Inhibitor) – Nubeqa Prior Authorization Policy
- Nubeqa® (darolutamide tablets – Bayer)

REVIEW DATE: 02/12/2025

OVERVIEW

Nubeqa, an androgen receptor inhibitor, is indicated for the treatment of adults for the following uses:[1]
- **Prostate cancer, metastatic castration-sensitive**.
- **Prostate cancer, metastatic, castration-sensitive**, in combination with docetaxel.
- **Prostate cancer, non-metastatic, castration-resistant**.

Guidelines

According to the National Comprehensive Cancer Network guidelines for **prostate cancer** (version 2.2025 – April 16, 2025), for non-metastatic, castration-resistant prostate cancer, androgen deprivation therapy (ADT) is continued to maintain castrate serum levels of testosterone (< 50 ng/dL).[2] Nubeqa, Erleada™ (apalutamide tablets) and Xtandi® (enzalutamide tablets and capsules) are all category 1 "Preferred" regimens if the prostate specific antigen doubling time is ≤ 10 months. For metastatic castration sensitive prostate cancer with high-volume synchronous or metachronous metastases, the guidelines recommend abiraterone, and Nubeqa as category 1 "Preferred" regimens in combination with ADT and docetaxel. Nubeqa is listed under "Other Recommended Regimens" when used in combination with ADT alone (category 2A). For low-volume synchronous or metachronous metastases Nubeqa in combination with ADT, with or without docetaxel, is a category 2B recommendation under "Other Recommended Regimens".

POLICY STATEMENT

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

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nubeqa is recommended in those who meet one of the following criteria:

FDA-Approved Indications

1. **Prostate Cancer – Metastatic, Castration-Sensitive.** Approve for 1 year if the patient meets BOTH of the following (A and B):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient meets ONE of the following (i or ii):
     - **i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
       Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate

subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).

ii. Patient has had a bilateral orchiectomy.

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

A) Patient is ≥ 18 years of age; AND

B) Patient meets ONE of the following (i or ii):

i. The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR

Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix subcutaneous injection), Orgovyx (relugolix tablets).

ii. Patient has had a bilateral orchiectomy.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Nubeqa is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Nubeqa® tablets [prescribing information]. Whippany, NJ: Bayer; June 2025.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 2.2025 – April 16, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 5, 2025.
3. The NCCN Drugs & Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on February 10, 2025. Search term: darolutamide.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Prostate Cancer – Metastatic, Castration-Sensitive**: In reference to docetaxel therapy, added new criteria "Patient has completed docetaxel therapy". Nubeqa is taken concurrently with docetaxel or can also be continued after docetaxel therapy.	07/19/2023
Annual Revision	**Prostate Cancer – Metastatic, Castration-Sensitive:** The criterion requiring the trial of gonadotropin-releasing hormone "agonist" was changed to "analog", which allows use of both agonists and antagonists. Firmagon and Orgovyx were added as examples in the Note. The separate criterion previously asking for concurrent use of medication with Firmagon was deleted since it is no longer needed. **Prostate Cancer – Non-Metastatic, Castration-Resistant:** The criterion requiring the trial of gonadotropin-releasing hormone "agonist" was changed to "analog", which allows use of both agonists and antagonists. Firmagon and Orgovyx were added as examples in the Note. The separate criterion previously asking for concurrent use of medication with Firmagon was deleted since it is no longer needed.	08/14/2024
Early Annual Revision	**Prostate Cancer – Metastatic, Castration-Sensitive:** Deleted criteria referring to concurrent docetaxel therapy or has completed docetaxel therapy based on guideline updates.	02/12/2025
Update	04/17/2025: The policy name was updated from "Oncology – Nubeqa PA Policy" to "Oncology (Oral - Androgen Receptor Inhibitor) – Nubeqa PA Policy".	N/A
Update	06/05/2025: Updated Overview section with new indication for Nubeqa and guidelines.	N/A

N/A – Not applicable.