VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Nubeqa Prior Authorization Policy
- Nubeqa® (darolutamide tablets – Bayer)

REVIEW DATE: 08/10/2022

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).

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 the following criteria (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** The medication is used concurrently with docetaxel; AND
   - **C)** Patient 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.** Patient has had a bilateral orchiectomy.

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

A) Patient is ≥ 18 years of age; AND
B) Patient 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.** 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; 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.

HISTORY

Type of Revision	Summary of Changes	Review 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 "agonist". Criterion was added for concurrent use with Firmagon (degarelix subcutaneous injection).	08/10/2022