PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 08/14/2024

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 4.2024 – May 17, 2024), 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 tablets and 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).

Dosing

For patients with hormone-sensitive metastatic prostate cancer, treated with Nubeqa in combination with docetaxel, the first of the 6 cycles of docetaxel should be administered within 6 weeks after the start of Nubeqa.[1] Treatment with Nubeqa may be continued until disease progression or unacceptable toxicity, even if a cycle of docetaxel is delayed, interrupted, or discontinued. Patients receiving Nubeqa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or have had a bilateral orchiectomy.

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 ALL of the following (A, B, and C):
   - **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 docetaxel; OR
     - **ii.** Patient has completed docetaxel therapy; AND
   - **C)** 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; October 2023.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – May 17, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed August 11, 2024.
3. The NCCN Drugs & Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on August 11, 2024. Search term: darolutamide.