

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):

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