

PRIOR AUTHORIZATION POLICY

- POLICY:** Oncology – Nubeqa Prior Authorization Policy
- Nubeqa (darolutamide tablets – Bayer HealthCare Pharmaceuticals Inc.)

REVIEW DATE: 08/26/2020

OVERVIEW

Nubeqa, an androgen receptor inhibitor, is indicated for the treatment of patients with non-metastatic, castration-resistant prostate cancer (nmCRPC).¹

GUIDELINES

According to the National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer, (version 2.2020 – May 21, 2020) for nmCRPC, androgen deprivation therapy (ADT) 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 especially if the prostate specific antigen doubling time (PSADT) is ≤ 10 months. Observation is noted as an option especially if the PSADT is > 10 months.

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 the following criteria:

FDA-Approved Indications

- 1. Prostate Cancer – Non-Metastatic, Castration-Resistant.** Approve for 3 years if the patient meets the following criteria (A or B):
 - A)** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
Note: Examples are Lupron (leuprolide for injection), Lupron Depot (leuprolide acetate for depot suspension), Trelstar (triptorelin pamoate for injectable suspension), Zoladex (goserelin acetate implant), Firmagon (degarelix for injection), Vantas (histrelin acetate subcutaneous implant).
 - B)** 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[®] [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceutical Inc.; July 2019.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 2.2020 – May 21, 2020). © 2020 National Comprehensive Cancer Network Inc. Available at: <http://www.nccn.org>. Accessed August 17, 2020.