# PRIOR AUTHORIZATION POLICY

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

**REVIEW DATE:** 08/14/2024

***INSTRUCTIONS FOR USE***

*THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.*

## CIGNA NATIONAL FORMULARY COVERAGE:

## 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.

- **Nubeqa® (darolutamide tablets (Bayer)**

**is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):**

### 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 COVERED

- **Nubeqa® (darolutamide tablets (Bayer)**

**is(are) considered experimental, investigational or unproven for ANY other use(s); 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.


## 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.<br>**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 |