



## PRIOR AUTHORIZATION POLICY

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

**REVIEW DATE:** 07/19/2023

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### **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. 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:<sup>1</sup>

- **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 1.2023 – September 16, 2022), for non-metastatic, castration-resistant prostate cancer, androgen deprivation therapy is continued to maintain castrate serum levels of testosterone (< 50 ng/dL).<sup>2</sup> 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.<sup>1</sup> 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 the following criteria (A, B, and C):

**A)** Patient is  $\geq 18$  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, 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  $\geq 18$  years of age; AND

**B)** Patient meets one of the following (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 COVERED**

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

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

**REFERENCES**

1. Nubeqa® tablets [prescribing information]. Whippany, NJ: Bayer; August 2022.
2. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed July 17, 2023.
3. The NCCN Drugs & Biologics Compendium. © 2023 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on July 16, 2023. Search term: darolutamide.

**HISTORY**

Type of Revision	Summary of Changes	Review Date
Early Annual Revision	<p><b>Prostate Cancer – Metastatic, Castration-Sensitive:</b> Indication and criteria were added due to FDA approval for this indication.</p> <p><b>Prostate Cancer – Non-Metastatic, Castration-Resistant:</b> The criterion requiring trial of gonadotropin-releasing hormone “analog” was revised to “agonist”. Criterion was added for concurrent use with Firmagon (degarelix subcutaneous injection).</p>	08/10/2022
Annual Revision	<p><b>Prostate Cancer – Metastatic, Castration-Sensitive:</b> 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.</p>	07/19/2023

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