UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 1291-6
Program	Prior Authorization/Notification
Medication	Nubeqa® (darolutamide)
P&T Approval Date	9/2019, 9/2020, 9/2021, 9/2022, 9/2023, 9/2024
Effective Date	12/1/2024

1. Background:

Nubeqa (darolutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC) and metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel. Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently while taking Nubeqa or should have had bilateral orchiectomy.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Nubeqa** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Prostate Cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Nubeqa** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of prostate cancer

      -AND-

      (2) **<u>One</u>** of the following:

         (a) **<u>Both</u>** of the following:

i. Disease is non-metastatic

-AND-

ii. Disease is castration-resistant or recurrent

-OR-

(b) **All** of the following:

i. Disease is metastatic

-AND-

ii. Disease is hormone-sensitive

-AND-

iii. Nubeqa will be used in combination with docetaxel

-AND-

(3) **One** of the following:

(a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

-OR-

(b) Patient has had bilateral orchiectomy

Authorization will be issued for 12 months.

2. **Reauthorization Criteria**

a. **Nubeqa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Nubeqa therapy

Authorization will be issued for 12 months.

C. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B.

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Nubeqa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; October 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/drug_compendium/content/. Accessed July 26, 2024.

Program	Prior Authorization/Notification – Nubeqa (darolutamide)
Change Control	
9/2019	New program
9/2020	Annual review with no changes to criteria. Updated references.
9/2021	Annual review with no changes to coverage criteria. Updated formatting and references.
9/2022	Annual review. Added criteria for metastatic hormone-sensitive prostate cancer (mHSPC) and updated background. Added state mandate disclaimer and updated references.
9/2023	Annual review with no changes to coverage criteria. Updated references.
9/2024	Annual review with no changes. Updated references.