UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2021 P 1291-3
Program	Prior Authorization/Notification
Medication	Nubeqa® (darolutamide)
P&T Approval Date	9/2019, 9/2020, 9/2021
Effective Date	12/1/2021; Oxford only: 12/1/2021

1. Background:

Nubeqa (darolutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer. 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. Patients less than 19 years of age

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. Prostate Cancer

1. Initial Authorization

a. **Nubeqa** will be approved based on **all** of the following criteria:

(1) Diagnosis of prostate cancer

-AND-

(2) Disease is non-metastatic

-AND-

(3) Disease is castration-resistant or recurrent

-AND-

(4) **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.

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.; January 2021.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 27, 2021.

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.