UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Nubeqa

Program	Prior Authorization
Medication	Nubeqa® (darolutamide)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	9/2019
Pharmacy and Therapeutics Approval Date	9/2020
Effective Date	11/2020

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.[1]

2. Coverage Criteria:

A. 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 castration-resistant or recurrent

-AND-

(3) Disease is non-metastatic

-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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Nubeqa** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Nubeqa therapy

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., July 2019.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed August7, 2020.

Program	Prior Authorization
Change Control	
Date	Change
9/2019	New program.
9/2020	Annual review with no changes to criteria. Updated references. Added Additional Clinical Rules section.