MEDICAL MUTUAL®

Drug Policy

Policy:	Nubeqa (darolutamide)	Annual Review Date: 06/16/2022 Last Revised Date: 06/16/2022

OVERVIEW

Nubeqa is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC).

Guidelines

According to the National Comprehensive Cancer Network (NCCN) guidelines for prostate cancer, (version 2.2019 – April 17, 2019) for nmCRPC, androgen deprivation therapy (ADT) is continued to maintain castrate serum levels of testosterone (< 50 ng/dL).[2] Observation is noted as an option especially if the prostate specific antigen (PSA) doubling time (PSADT) is > 10 months. Erleada (apalutamide tablets) and Xtandi® (enzalutamide capsules) are category 1 recommended options especially if the PSADT is ≤ 10 months. Other secondary hormone therapy is also an option if PSADT is ≤ 10 months (category 2A): for non-metastatic (M0) CRPC, some of the options are nilutamide, flutamide, bicalutamide, ketoconazole, corticosteroids.

POLICY STATEMENT

This policy involves the use of Nubeqa. Prior authorization is recommended for pharmacy benefit coverage of Nubeqa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Nubeqa as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Nubeqa be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Nubeqa must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Nubeqa is recommended in those who meet the following criteria:

1. **Prostate Cancer – Non-Metastatic, Castration-Resistant (nmCRPC)**
   Criteria. *Patient must meet the following criteria*

A. Used in combination with androgen deprivation therapy (ADT) to maintain castrate serum levels of testosterone (< 50 ng/dL); OR
B. Patient has had a bilateral orchiectomy.

2. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

3. **Patient has been started on Nubeqa**
Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Nubeqa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

REFERENCES

1. Nubeqa [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceutical Inc.; January 2021.
2. The NCCN Drugs and Biologics Compendium. ©2022 National Comprehensive Cancer Network Inc. Available at: http://www.nccn.org. Accessed 14 June 2022.
3. darolutamide. In: DRUGDEX [online database]. Truven Health Analytics. Greenwood Village, CO. Last updated 27 April 2022. Accessed 14 June 2022.