Reference number(s)
3147-A

Specialty Guideline Management
Nubeqa

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Nubeqa	darolutamide

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-approved Indications[1]

- Nubeqa is indicated for the treatment of adult patients with non-metastatic castration-resistant prostate cancer (nmCRPC).
- Nubeqa is indicated for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.

Compendial Uses[2]

Prostate Cancer

All other indications are considered experimental/investigational and not medically necessary.

Exclusions

Coverage will not be provided if the requested medication is used in combination with a second-generation oral anti-androgen (e.g., apalutamide [Erleada]) or an oral androgen metabolism inhibitor (e.g., abiraterone acetate [Zytiga]).

Coverage Criteria

Prostate Cancer[1,2]

Authorization of 12 months may be granted when either of the following criteria are met:

- The member has non-metastatic castration-resistant prostate cancer and the member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).
- The member has metastatic castration-sensitive prostate cancer and meets both of the following criteria:
    - The requested medication will be used in combination with docetaxel
    - The member has had a bilateral orchiectomy or will be using the requested medication in combination with a LHRH agonist or antagonist.

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in the coverage criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Nubeqa [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc.; October 2023.
2. The NCCN Drugs & Biologics Compendium™ © 2024 National Comprehensive Cancer Network, Inc. https://www.nccn.org Accessed July 2, 2024.