

5.21.131

Section:	Prescription Drugs	Effective Date:	October 1, 2025
Subsection:	Antineoplastic Agents	Original Policy Date:	August 16, 2019
Subject:	Nubeqa	Page:	1 of 5

Last Review Date: September 19, 2025

Nubeqa

Description

Nubeqa (darolutamide)

Background

Nubeqa (darolutamide) is an androgen receptor (AR) inhibitor. Nubeqa competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. Nubeqa is thought to decrease prostate cancer cell proliferation and tumor volume in prostate cancer (1).

Regulatory Status

FDA-approved indications: Nubeqa is an androgen receptor inhibitor indicated for the treatment of adult patients with: (1)

- non-metastatic castration-resistant prostate cancer (nmCRPC).
- metastatic castration-sensitive prostate cancer (mCSPC).
- metastatic castration-sensitive prostate cancer (mCSPC) in combination with docetaxel.

Patients receiving Nubeqa should also receive a gonadotropin-releasing hormone (GnRH) agonist or antagonist concurrently or should have had a bilateral orchiectomy (1).

Nubeqa can be harmful to a developing fetus and can cause loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose of Nubeqa (1).

The safety and effectiveness of Nubeqa in pediatric and female patients have not been established (1).

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Related policies

Erleada, Nilandron, Orgovyx, Xtandi, Yonsa, Zytiga

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nubeqa may be considered **medically necessary** if the conditions indicated below are met.

Nubeqa may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Gender Male

Diagnoses

Patient must have **ONE** of the following:

1. Non-metastatic castration-resistant prostate cancer (nmCRPC)
2. Metastatic castration-sensitive prostate cancer (mCSPC)

AND ONE of the following for **ALL** diagnoses:

1. Patient is receiving a gonadotropin-releasing hormone (GnRH) agonist or antagonist
2. Patient has had a bilateral orchiectomy

AND ALL of the following for **ALL** diagnoses:

1. **NO** dual therapy with another Prior Authorization (PA) androgen receptor inhibitor (see Appendix 1)
2. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Nubeqa and for 1 week after the last dose

Prior – Approval *Renewal* Requirements

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Same as above

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 360 tablets per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Nubeqa (darolutamide) is an androgen receptor (AR) inhibitor. Nubeqa competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. Nubeqa is thought to decrease prostate cancer cell proliferation and tumor volume in prostate cancer. The safety and effectiveness of Nubeqa in pediatric and female patients have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Nubeqa while maintaining optimal therapeutic outcomes.

References

1. Nubeqa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; June 2025.
2. NCCN Drugs & Biologics Compendium[®] Darolutamide 2025. National Comprehensive Cancer Network, Inc. Accessed on August 12, 2025.

Policy History

Date	Action
August 2019	Addition to PA

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September 2019	Annual review
December 2019	Annual review
June 2020	Annual review
March 2021	Annual editorial review and reference update
June 2021	Annual review and reference update
August 2022	Per PI update, addition of indication: metastatic hormone-sensitive prostate cancer (mHSPC). Reworded contraception requirement for consistency
December 2022	Annual review and reference update
September 2023	Annual review and reference update
December 2023	Annual review and reference update
March 2024	Annual review and reference update
December 2024	Annual review and reference update
June 2025	Per PI update, added indication of mCSPC and removed dual docetaxel requirement for mCSPC. Also changed requirement of GnRH analog to a GnRH agonist or antagonist
September 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on September 19, 2025 and is effective on October 1, 2025.

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Appendix 1 - List of PA Androgen Receptor Inhibitors

Generic Name	Brand Name
abiraterone	Yonsa
abiraterone	Zytiga
abiraterone/niraparib	Akeega
apalutamide	Erleada
darolutamide	Nubeqa
enzalutamide	Xtandi
nilutamide	Nilandron