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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	August 16, 2019
Subject:	Nubeqa	**Page:**	1 of 5

Last Review Date: March 8, 2024

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 hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.

Patients receiving Nubeqa should also receive a gonadotropin-releasing hormone (GnRH) analog 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).

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 hormone-sensitive prostate cancer (mHSPC)
    a. Used in combination with docetaxel

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

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

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

1. **NO** dual therapy with another 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

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.; October 2023.
2. NCCN Drugs & Biologics Compendium® Darolutamide 2024. National Comprehensive Cancer Network, Inc. Accessed on January 18, 2024.

Policy History

Date	Action
August 2019	Addition to PA

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.

Appendix 1 - List of Androgen Receptor Inhibitors

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