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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 indication: Nubeqa is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (1).

Patients receiving Nubeqa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had 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** for male patients 18 years of age or older for the treatment of Non-Metastatic Castration-Resistant Prostate Cancer (NM-CRPC) and if the conditions indicated below are met.

Nubeqa may be considered **investigational** in patients who are female, in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Gender Male

Diagnoses

Patient must have the following:

Non-Metastatic Castration-Resistant Prostate Cancer (NM-CRPC)

AND ONE of the following:

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

AND ALL of the following:

1. **NO** dual therapy with another androgen receptor inhibitor (see Appendix 1)
2. Prescriber agrees to advise males with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose of Nubeqa

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.; January 2021.

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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 12, 2021 and is effective on April 1, 2021.

Appendix 1 - List of Androgen Receptor Inhibitors

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