



## **NUBEQA (darolutamide)**

### **RATIONALE FOR INCLUSION IN PA PROGRAM**

#### **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).

#### **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.



**BlueCross.  
BlueShield.**

Federal Employee Program.

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**References**

1. Nubeqa [package insert]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; June 2025.
2. NCCN Drugs & Biologics Compendium<sup>®</sup> Darolutamide 2025. National Comprehensive Cancer Network, Inc. Accessed on June 4, 2025.