Commercial/Healthcare Exchange PA Criteria

Effective: October 18th, 2019

Prior Authorization: Nubeqa

Products Affected: Nubeqa (darolutamide) oral tablets

Medication Description: Nubeqa (darolutamide) is androgen receptor (AR) inhibitor and competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. In vitro, darolutamide decreased prostate cancer cell proliferation and functioned as a progesterone receptor (PR) antagonist. The adverse reactions profile of darolutamide is thought to differ from other drugs in this class due to its distinct structure and characteristics that result in low penetration if the blood-brain barrier and low binding affinity for gamma-aminobutyric acid type A receptors in preclinical studies.

Covered Uses: Treatment of patients with non-metastatic castration-resistant prostate cancer

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis

Age Restrictions: 18 years of age and older

Prescriber Restrictions: Prescribed by or in consultation with an oncologist.

Coverage Duration: 3 years

Other Criteria:

Nubeqa (darolutamide) may be considered medically necessary when all of the following selection criteria are met:

1. The patient has a diagnosis of non-metastatic castration-resistant prostate cancer.

References:

1. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2019
2. Nubeqa (darolutamide) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc; July 2019.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	10/07/2019