Reference number(s)
3147-A

SPECIALTY GUIDELINE MANAGEMENT

NUBEQA (darolutamide)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

1. Nubeqa is indicated for the treatment of adult patients with non-metastatic castration-resistant prostate cancer.
2. Nubeqa is indicated for the treatment of adult patients with metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel.

All other indications are considered experimental/investigational and not medically necessary.

II. EXCLUSIONS

Coverage will not be provided if the requested medication is used in combination with a second-generation oral anti-androgen (e.g., apalutamide [Erleada]) or an oral androgen metabolism inhibitor (e.g., abiraterone acetate [Zytiga]).

III. CRITERIA FOR INITIAL APPROVAL

Prostate Cancer

Authorization of 12 months may be granted when either of the following criteria are met:

1. The member has non-metastatic castration-resistant prostate cancer and the member has had a bilateral orchiectomy or will be using the requested medication in combination with a GnRH analog.
2. The member has metastatic hormone-sensitive prostate cancer and meets both of the following criteria:
   i. The requested drug will be used in combination with docetaxel
   ii. The member has had a bilateral orchiectomy or will be using the requested medication in combination with a GnRH analog.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Nubeqa [package insert]. Whippany, NJ: Bayer Healthcare Pharmaceuticals Inc.; August 2022.