

darolutamide tablet (NUBEQA)

Diagnoses Considered for Coverage:

- Castration-resistant prostate cancer – nonmetastatic (nmCRPC)
- Hormone sensitive, metastatic, prostate cancer (mHSPC)

Coverage Criteria:

For diagnosis of nonmetastatic castrate resistant prostate cancer (nmCRPC):

- Patient's PSA level rising despite androgen deprivation therapy (ADT), **and**
- Not being used with Erleada, Xtandi, Yonsa, or abiraterone (Zytiga), **and**
- Dose does not exceed 1200 mg per day, **and**
- One of the following androgen deprivation therapies (ADT):
 - Currently receiving an LHRH agonist: Zoladex (goserelin), Vantas (histrelin), Lupron (leuprolide), Trelstar (triptorelin), or
 - Currently receiving Firmagon (degarelix), or
 - Patient had testes removed (bilateral orchiectomy)

For diagnosis of metastatic hormone sensitive prostate cancer (mHSPC):

- Being used in combination with docetaxel, **and**
- Not being used with Erleada, Xtandi, Yonsa, or abiraterone (Zytiga), **and**
- Dose does not exceed 1200 mg per day, **and**
- One of the following androgen deprivation therapies (ADT):
 - Currently receiving an LHRH agonist: Zoladex (Goserelin), Vantas (histrelin), Lupron (leuprolide), Trelstar (triptorelin), or
 - Currently receiving Firmagon (degarelix), or
 - Patient had testes removed (bilateral orchiectomy)

Coverage Duration: one year

Effective Date: 11/29/2023