Prior Authorization (PA) and Medical Exception Guide for NUBEQA® (darolutamide)

Common PA Criteria for NUBEQA*

Most health plans require PAs for oncology products, including NUBEQA for non-metastatic castration-resistant prostate cancer (nmCRPC) and metastatic hormone-sensitive prostate cancer (mHSPC).[1] **The prescriber may need to obtain authorization before coverage for NUBEQA can be confirmed.**

PA criteria can vary by plan and many plans will have a specific PA request form with required information available on their website.

PA Tips

It is important to **provide complete and accurate information** for every PA to **streamline the process and avoid delays**

- **ICD-10-CM diagnosis codes most commonly used to describe the patient's diagnosis[2]:**

  mHSPC
  - C61 (malignant neoplasm of the prostate)
  - Z19.1 (hormone-sensitive malignancy status)
  - Z51.11 (encounter for antineoplastic chemotherapy)
  - C78.0-C78.8 and C79.0-C79.9 (secondary malignant neoplasms)

  nmCRPC
  - C61 (malignant neoplasm of the prostate)
  - Z19.2 (hormone-resistant malignancy status)
- **Commonly requested lab values:**
  - PSA (prostate-specific antigen)
  - Diagnostic testing, ie, eGFR (used to establish appropriate NUBEQA dosing), testosterone serum levels
  - Radiology reports, ie, PET scan, MRI, CT scans, x-rays, etc
- **Provide NCCN Guidelines®**
- **If applicable, indicate current and previously prescribed medications the patient has tried, as well as, those the patient cannot take due to drug-drug interactions (chemotherapy, other androgen receptor inhibitors, etc)**
  - Specify if the patient has taken NUBEQA (including free samples) and provide an explanation of the patient's experience when applicable
  - Include any additional supporting documentation that validates the patient's diagnosis and supports treatment with NUBEQA
- **Plans may require a formal request from the physician via a medical exception letter with additional evidence. A sample medical exception letter and sample appeal letter can be found at www.NUBEQAhcp.com**

NUBEQA Dosing and Supply[1]

300 mg tablet

NDC: 50419-0395-01
Supplied in: 120-count bottle

Recommended dosage:
Two 300 mg tablets administered twice daily with food for a total daily dose of 1200 mg

INDICATIONS

NUBEQA® (darolutamide) is an androgen receptor inhibitor indicated for the treatment of adult patients with:

- Non-metastatic castration-resistant prostate cancer (nmCRPC)
- Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel

IMPORTANT SAFETY INFORMATION

Warnings & Precautions

Ischemic Heart Disease – In a study of patients with nmCRPC (ARAMIS), ischemic heart disease occurred in 3.2% of patients receiving NUBEQA versus 2.5% receiving placebo, including Grade 3-4 events in 1.7% vs. 0.4%, respectively. Ischemic events led to death in 0.3% of patients receiving NUBEQA vs. 0.2% receiving placebo. In a study of patients with mHSPC (ARASENS), ischemic heart disease occurred in 3.2% of patients receiving NUBEQA with docetaxel vs. 2% receiving placebo with docetaxel, including Grade 3-4 events in 1.3% vs. 1.1%, respectively. Ischemic events led to death in 0.3% of patients receiving NUBEQA with docetaxel vs. 0% receiving placebo with docetaxel. Monitor for signs and symptoms of ischemic heart disease. Optimize management of cardiovascular risk factors, such as hypertension, diabetes, or dyslipidemia. Discontinue NUBEQA for Grade 3-4 ischemic heart disease.

Please see additional Important Safety Information on next page and full Prescribing Information.

CT=computed tomography; eGFR=estimated glomerular filtration rate; FGARI=first-generation androgen receptor inhibitor; ICD-10-CM=*International Classification of Diseases, Tenth Revision, Clinical Modification*; MRI=magnetic resonance imaging; NCCN=National Comprehensive Cancer Network; NDC=National Drug Code; PET=positron emission tomography; SGARI=second-generation androgen receptor inhibitor.

*Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage will result. Customers should consult with their payers for all relevant coverage and coding.

NUBEQA® (darolutamide) 300 mg tablets

Access Services by Bayer™

Access Services by Bayer™ offers best-in-class support services to help your patients throughout their treatment journey with NUBEQA.

PA Support for NUBEQA Through CoverMyMeds®*:

1. Log in or create your account at **CoverMyMeds.com**. Then select **New Request** and enter **NUBEQA**
2. For PA support, select **Start PA** then complete the required fields
   - For appeals and medical exception support, select **Start Enrollment** then complete the required fields
   - Fill out the comments section on the PA form with **all relevant information** to support the therapy approval request

Tip

3. Click **Submit** to complete the electronic PA or enrollment process
4. **Check** your patient's case status, including the PA status, by selecting **Cases** on the left side of the portal at any time

For additional questions or support with the platform:

Live Chat: www.covermymeds.com
Phone: 1-800-288-8374 (M-F, 9 AM-6 PM ET)

Resources: go.covermymeds.com/specialtydemo

Additional patient support is available at 1-800-288-8374 and **www.NUBEQAhcp.com**

Contact your Field Reimbursement Manager (FRM) for any additional questions.

FRM name _____ FRM phone # _____

FRM email _____

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings & Precautions (cont'd)

Seizure – In ARAMIS, Grade 1-2 seizure occurred in 0.2% of patients receiving NUBEQA vs. 0.2% receiving placebo. Seizure occurred 261 and 456 days after initiation of NUBEQA. In ARASENS, seizure occurred in 0.6% of patients receiving NUBEQA with docetaxel, including one Grade 3 event, vs. 0.2% receiving placebo with docetaxel. Seizure occurred 38 to 340 days after initiation of NUBEQA. It is unknown whether anti-epileptic medications will prevent seizures with NUBEQA. Advise patients of the risk of developing a seizure while receiving NUBEQA and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others. Consider discontinuation of NUBEQA in patients who develop a seizure during treatment.

Embryo-Fetal Toxicity – Safety and efficacy of NUBEQA have not been established in females. NUBEQA can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception during treatment with NUBEQA and for 1 week after the last dose.

Adverse Reactions

In ARAMIS, serious adverse reactions occurred in 25% of patients receiving NUBEQA vs. 20% of patients receiving placebo. Serious adverse reactions in ≥1% of patients who received NUBEQA included urinary retention, pneumonia, and hematuria. Fatal adverse reactions occurred in 3.9% of patients receiving NUBEQA vs. 3.2% of patients receiving placebo. Fatal adverse reactions in patients who received NUBEQA included death (0.4%), cardiac failure (0.3%), cardiac arrest (0.2%), general physical health deterioration (0.2%), and pulmonary embolism (0.2%). The most common adverse reactions (>2% with a ≥2% increase over placebo), including laboratory test abnormalities, were increased AST, decreased neutrophil count, fatigue, increased bilirubin, pain in extremity, and rash. Clinically relevant adverse reactions occurring in ≥2% of patients treated with NUBEQA included ischemic heart disease and heart failure.

In ARASENS, serious adverse reactions occurred in 45% of patients receiving NUBEQA with docetaxel vs. 42% of patients receiving placebo with docetaxel. Serious adverse reactions in ≥2% of patients who received NUBEQA with docetaxel included febrile neutropenia (6%), decreased neutrophil count (2.8%), musculoskeletal pain (2.6%), and pneumonia (2.6%). Fatal adverse reactions occurred in 4% of patients receiving NUBEQA with docetaxel vs. 4% of patients receiving placebo with docetaxel. Fatal adverse reactions in patients who received NUBEQA included COVID-19/COVID-19 pneumonia (0.8%), myocardial infarction (0.3%), and sudden death (0.3%). The most common adverse reactions (≥10% with a ≥2% increase over placebo with docetaxel) were constipation, rash, decreased appetite, hemorrhage, increased weight, and hypertension. The most common laboratory test abnormalities (≥30%) were anemia, hyperglycemia, decreased lymphocyte count, decreased neutrophil count, increased AST, increased ALT, and hypocalcemia. Clinically relevant adverse reactions in <10% of patients who received NUBEQA with docetaxel included fractures, ischemic heart disease, seizures, and drug-induced liver injury.

Drug Interactions

Effect of Other Drugs on NUBEQA – Combined P-gp and strong or moderate CYP3A4 inducers decrease NUBEQA exposure, which may decrease NUBEQA activity. Avoid concomitant use.

Combined P-gp and strong CYP3A4 inhibitors increase NUBEQA exposure, which may increase the risk of NUBEQA adverse reactions. Monitor more frequently and modify NUBEQA dose as needed.

Effects of NUBEQA on Other Drugs – NUBEQA inhibits breast cancer resistance protein (BCRP) transporter. Concomitant use increases exposure (AUC) and maximal concentration of BCRP substrates, which may increase the risk of BCRP substrate-related toxicities. Avoid concomitant use where possible. If used together, monitor more frequently for adverse reactions, and consider dose reduction of the BCRP substrate.

NUBEQA inhibits OATP1B1 and OATP1B3 transporters. Concomitant use may increase plasma concentrations of OATP1B1 or OATP1B3 substrates. Monitor more frequently for adverse reactions and consider dose reduction of these substrates.

Review the Prescribing Information of drugs that are BCRP, OATP1B1, and OATP1B3 substrates when used concomitantly with NUBEQA.

Please see additional Important Safety Information on previous page and full Prescribing Information.

*CoverMyMeds is an independent party.

References: 1. NUBEQA [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; October 2023.
2. ICD-10-CM October 1, 2023 update. Centers for Disease Control and Prevention. October 1, 2023. Accessed October 19, 2023. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2024/

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