PRIOR AUTHORIZATION AND MEDICAL EXCEPTION GUIDE FOR NUBEQA® (darolutamide)

Support to help simplify and streamline the PA process

Dick is an actual NUBEQA patient enrolled in Access Services by Bayer.

Most health plans require PAs for oncology products, including NUBEQA. The prescriber may need to obtain authorization before coverage can be confirmed. It is important to provide complete and accurate information for every PA to help streamline the process and avoid delays.

Use this 3-step process to help your patients receive NUBEQA as prescribed:

1

Determine if a PA is needed:
Conduct a benefit investigation through Access Services by Bayer™.

2

Initiate the PA process:
Review the PA Checklist on page 3 before submitting a PA or exception request.

3

Follow up:
Seek support when appealing an adverse determination, if needed.

Enroll your NUBEQA patients in Access Services by Bayer™ to receive support for the PA and appeals process, every step of the way.

INDICATIONS

NUBEQA is an androgen receptor inhibitor indicated for the treatment of adult patients with:

- non-metastatic castration-resistant prostate cancer (nmCRPC)
- metastatic castration-sensitive prostate cancer (mCSPC)
- metastatic castration-sensitive prostate cancer (mCSPC) in combination with docetaxel

IMPORTANT SAFETY INFORMATION

Warnings & Precautions

Ischemic Heart Disease – Ischemic heart disease, including fatal cases, occurred in patients receiving NUBEQA.

In a pooled analysis of ARAMIS and ARANOTE, ischemic heart disease occurred in 3.4% of patients receiving NUBEQA and 2.2% receiving placebo, including Grade 3-4 events in 1.4% and 0.3%, respectively. Ischemic events led to death in 0.4% of patients receiving NUBEQA and 0.4% receiving placebo.

In ARASENS, ischemic heart disease occurred in 3.2% of patients receiving NUBEQA with docetaxel and 2% receiving placebo with docetaxel, including Grade 3-4 events in 1.3% and 1.1%, respectively. Ischemic events led to death in 0.3% of patients receiving NUBEQA with docetaxel and 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.

Seizure – Seizure occurred in patients receiving NUBEQA.

In a pooled analysis of ARAMIS and ARANOTE, Grade 1-3 seizure occurred in 0.2% of patients receiving NUBEQA. Seizure occurred from 261 to 665 days after initiation of NUBEQA.

In ARASENS, seizure occurred in 0.8% of patients receiving NUBEQA with docetaxel, including two Grade 3 events. Seizure occurred from 38 to 1754 days after initiation of NUBEQA.

PA=prior authorization.

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

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Tips for completing and filing a PA

- **Recognize that PA criteria for NUBEQA can vary by plan and may change frequently**
- **Remember, the plan may require a specific form.** CoverMyMeds® offers payer-specific PA request forms for NUBEQA. CoverMyMeds is an online platform that can assist with the PA process
- **Consider submitting an electronic PA (ePA). ePAs can be submitted 3x faster than manual PAs.**[3] Review the tab at right to learn about the advantages of ePA vs fax
- **Use appropriate and specific ICD-10-CM diagnosis codes,** such as[4]:

mCSPC

C61 (malignant neoplasm of the prostate)
Z19.1 (hormone-sensitive malignancy status)
Z51.11 (encounter for antineoplastic chemotherapy)—*if applicable*
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)

- **Provide clinical details to support the medical necessity of NUBEQA.** Ensure the information provided fully supports the prescriber's rationale for prescribing NUBEQA. Consider proactively submitting a Letter of Medical Necessity
- **Reinforce medical necessity with clinical guidelines**, such as the most recent NCCN Guidelines® (available at NCCN.org), which can be attached to a PA request submission for NUBEQA

Requesting a medical exception

A medical exception may be needed when the patient's situation fails to meet all coverage criteria for NUBEQA, for example:

- NUBEQA is non-formulary
- A non-standard dosing regimen or quantity has been prescribed
- The plan requires step therapy, ie, trial and failure of another product
- A new or expanded indication approval is not yet reflected in the plan's coverage criteria

A plan may use the same form for PA and medical exception requests, or a separate form may be required.

Appealing a PA denial

A PA request may be rejected for many reasons, including clerical errors and incomplete form fields. Carefully review and address specific reasons for the denial provided in payer communications. Contact the payer for clarification, if needed. Appeal processes can vary by payer, and timely filing is crucial.

80% of appealed PAs are approved[1]

Review the tab at right to learn about the benefits of submitting an ePA vs fax. To streamline the process, CoverMyMeds can automatically populate an ePA appeals form.

For helpful resources to support the PA process, including a Letter of Medical Necessity, an Appeal Checklist, and a Sample Appeal Letter, visit www.NUBEQAhcp.com/resources/for-your-practice

IMPORTANT SAFETY INFORMATION (cont'd)

Warnings & Precautions (cont'd)

Seizure (cont'd) – 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 – The 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.

~50%
of submitted ePAs received a determination

within
5 MINUTES[1]
Faxed submissions required ≥1 day[2]

ePA support for NUBEQA through CoverMyMeds:

CoverMyMeds offers payer-specific forms, a centralized dashboard with real-time updates, live ePA and appeals support, and more.

Log in or create your account at **CoverMyMeds.com**. Then select **New Request** and enter **NUBEQA**

1. For ePA support, select **Start PA** then complete the required fields
   - For appeals and medical exception support, select **Start Enrollment** then complete the required fields

Tip – Fill out the comments section on the ePA form with **all relevant information** to support the therapy approval request

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

ePAs can be submitted 3X FASTER than manual PAs[3]

For additional questions or support with the platform:

Live Chat: www.CoverMyMeds.com
Phone: 1-800-288-8374
Resources: go.CoverMyMeds.com/specialtydemo

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PA submission checklist for NUBEQA*

1 PREPARE FOR PA SUBMISSION:

- ☐ Review the patient's coverage policy or PA criteria for NUBEQA and note any specific clinical requirements (eg, lab values, radiology results, ADT)
- ☐ Identify if an exception may be needed
- ☐ Confirm that the patient will be receiving a GnRH agonist or antagonist or has undergone a bilateral orchiectomy[5]
- ☐ Check if the payer requires a specific PA request form for NUBEQA

Contact Access Services by Bayer or your FRM for assistance. CoverMyMeds offers payer-specific PA forms for NUBEQA.

2 COMPLETE THE PA REQUEST, INCLUDING:

- ☐ Appropriate and specific ICD-10-CM diagnosis codes, including secondary codes
- ☐ Initial date of prostate cancer diagnosis
- ☐ Key laboratory test values, imaging results, and surgical outcomes (eg, PSA, serum testosterone, eGFR, radiograph, CT, MRI, PET scan, pathology report)
- ☐ Treatment history for prostate cancer, including medication dosage regimens and start/stop dates (IMPORTANT: Specify if the patient has taken NUBEQA, including free samples, and describe the patient's experience)
- ☐ Contraindications and intolerances to medications
- ☐ Information about GnRH agonist or antagonist use or bilateral orchiectomy[5]
- ☐ (For NUBEQA combination therapy with docetaxel in mCSPC only) Evidence of upcoming, current, or past treatment with docetaxel[5]
- ☐ Medication information for NUBEQA (Specify the complete regimen, including dosage form, strength, frequency, route of administration, and quantity of NUBEQA for the patient):
  - NUBEQA is supplied in a 120-count bottle (NDC: 50419-0395-01)[5]

Recommended dosage[5]:
Two 300 mg tablets administered twice daily with food for a total daily dose of 1200 mg

Provide detailed information to support the medical necessity of NUBEQA. Attach supporting documentation, such as office notes, clinical guidelines, a letter of medical necessity, and the prescribing information for NUBEQA to the PA submission.

3 SUBMIT THE PA REQUEST:

- ☐ Confirm the correct plan-specific form was selected
- ☐ Check that all required fields have been completed
- ☐ Attach supporting documentation (check the Document Upload section in CoverMyMeds)
- ☐ Ensure the PA request will be submitted to the patient's pharmacy benefit administrator
- ☐ Click "Submit PA Form" on CoverMyMeds or fax to the payer

After submission, follow up with the payer as needed. Use CoverMyMeds to check your patient's case status, including the PA status, by Selecting "Cases" on the left side of the portal at any time.

ADT=androgen deprivation therapy; CT=computed tomography; eGFR=estimated glomerular filtration rate; FRM=Field Reimbursement Manager; GnRH=gonadotropin-releasing hormone; ICD-10-CM=*International Classification of Diseases, 10th Revision, Clinical Modification*; mCSPC=metastatic castration-sensitive prostate cancer; MRI=magnetic resonance imaging; NCCN=National Comprehensive Cancer Network; NDC=National Drug Code; nmCRPC=non-metastatic castration-resistant prostate cancer; PET=positron emission tomography; PSA=prostate-specific antigen.

*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.

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions

In ARAMIS, serious adverse reactions occurred in 25% of patients receiving NUBEQA and in 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 and 3.2% of patients receiving placebo.

Let Bayer support you with PAs and appeals so you can focus on your patient's NUBEQA treatment.

Your Bayer FRM & Access Services by Bayer™ are here to help with end-to-end PA process education and support, including assistance with appeals.

Need more information? Connect with your Bayer FRM:

FRM name

FRM phone number

FRM email

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Access Services by Bayer is here to help your patients receive their prescribed NUBEQA

Complete these quick steps to allow your patients to obtain assistance from Access Services by Bayer:

1. **Obtain an enrollment form using one of these methods:**
   - **CoverMyMeds.com:** Search for NUBEQA and select "enrollment form"
   - **A Bayer Sales Consultant:** Request a printed enrollment form
   - **NUBEQAhcp.com:** Select "Resources, For Your Practice" to download the Patient Services Request Form
2. **Ensure the form is signed and dated by the prescriber and the patient.** Both the prescriber and the patient must sign the enrollment form before Access Services by Bayer can help. A patient can sign:
   - In-office • Via email • With Patient HIPAA Authorization Form

   Enrollment is valid for 5 years.
3. **Submit the form electronically** at CoverMyMeds or fax the printed form to 1-800-390-1826

IMPORTANT SAFETY INFORMATION (cont'd)

Adverse Reactions (cont'd)

Fatal adverse reactions that occurred in ≥2 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 (>2% with a ≥2% increase compared to placebo) adverse reactions, including laboratory test abnormalities, were increased AST (23%), decreased neutrophil count (20%), fatigue (16%), increased bilirubin (16%), pain in extremity (6%), and rash (4%). Clinically relevant adverse reactions occurring in 2% or more of patients treated with NUBEQA included ischemic heart disease (4%) and heart failure (2.1%).

In ARANOTE, serious adverse reactions occurred in 24% of patients receiving NUBEQA. Serious adverse reactions in ≥1% of patients who received NUBEQA included pneumonia (2%), urinary tract infection (1.8%), musculoskeletal pain (1.6%), hemorrhage (1.6%), arrhythmias (1.3%), and spinal cord compression (1.1%). Fatal adverse reactions occurred in 4.7% of patients receiving NUBEQA and those that occurred in ≥2 patients included sepsis (1.1%), craniocerebral injury (0.4%), and myocardial infarction (0.4%). The most common (≥10% with a ≥2% increase compared to placebo) adverse reaction is urinary tract infection (12%). The most common laboratory test abnormalities (≥15% with a ≥5% increase over placebo) are increased AST (32%), increased ALT (28%), increased bilirubin (17%), and decreased neutrophil count (16%). Clinically relevant adverse reactions in <10% of patients who received NUBEQA included arrhythmia (8.8%), pneumonia (3.6%), and myocardial infarction (0.7%).

In ARASENS, serious adverse reactions occurred in 45% of patients receiving NUBEQA with docetaxel. Serious adverse reactions in ≥2% of patients who received NUBEQA with docetaxel included febrile neutropenia (6%), neutrophil count decreased (2.8%), musculoskeletal pain (2.6%) and pneumonia (2.6%). Fatal adverse reactions occurred in 4% of patients receiving NUBEQA with docetaxel. Fatal adverse reactions in ≥2 patients who received NUBEQA included COVID-19/COVID-19 pneumonia (0.8%), myocardial infarction (0.3%), and sudden death (0.3%). The most common (≥10% with a ≥2% increase over placebo with docetaxel) adverse reactions are constipation (23%), rash (20%), decreased appetite (19%), hemorrhage (18%), increased weight (18%), and hypertension (14%). The most common laboratory test abnormalities (≥30%) are anemia (72%), hyperglycemia (57%), decreased lymphocyte count (52%), decreased neutrophil count (49%), increased AST (40%), increased ALT (37%), and hypocalcemia (31%). Clinically relevant adverse reactions in <10% of patients who received NUBEQA with docetaxel included fractures (8%), ischemic heart disease (3.2%), seizures (0.6%), and drug-induced liver injury (0.3%).

Drug Interactions

Effect of Other Drugs on NUBEQA – Concomitant use of NUBEQA with a combined P-gp and strong or moderate CYP3A4 inducer decreases darolutamide exposure which may decrease NUBEQA activity. Avoid concomitant use of NUBEQA with combined P-gp and strong or moderate CYP3A4 inducers.

Concomitant use of NUBEQA with a combined P-gp and strong CYP3A4 inhibitor increases darolutamide exposure which may increase the risk of NUBEQA adverse reactions. Monitor patients more frequently for NUBEQA adverse reactions and modify NUBEQA dosage as needed.

Effects of NUBEQA on Other Drugs – NUBEQA is an inhibitor of BCRP transporter. Concomitant use of NUBEQA increases the AUC and C_{max} of BCRP substrates, which may increase the risk of BCRP substrate-related toxicities. Avoid concomitant use with drugs that are BCRP substrates where possible. If used together, monitor patients more frequently for adverse reactions, and consider dose reduction of the BCRP substrate drug.

NUBEQA is an inhibitor of OATP1B1 and OATP1B3 transporters. Concomitant use of NUBEQA may increase the plasma concentrations of OATP1B1 or OATP1B3 substrates. Monitor patients more frequently for adverse reactions of these drugs and consider dose reduction while patients are taking NUBEQA.

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

Please see full Prescribing Information.

CoverMyMeds is an independent party.

References: 1. Data on file. Bayer HealthCare Pharmaceuticals, Inc.; Whippany, NJ. **2.** Electronic prior authorization. CoverMyMeds. Accessed April 28, 2025. https://insights.covermymeds.com/medication-access-report/2020/electronic-prior-authorization **3.** Optimizing provider workflows. CoverMyMeds. Accessed April 28, 2025. https://www.covermymeds.health/who-we-serve/provider **4.** ICD-10-CM tabular list of diseases and injuries. April 1, 2025 update. Centers for Disease Control and Prevention. Accessed April 28, 2025. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2025-Update **5.** NUBEQA [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; June 2025.

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