Access Services by Bayer™

NUBEQA® (darolutamide) 300 mg tablets

Patient Support Program Resources

PHONE		1-800-288-8374
FAX		1-800-390-1826
ONLINE		www.NUBEQAhcp.com

Information provided in this resource is for informational purposes only and does not guarantee that codes will be appropriate or that coverage and reimbursement will result. Customers should consult with their payers for all relevant coverage, coding, and reimbursement requirements. It is the sole responsibility of the provider to select proper codes and ensure the accuracy of all claims used in seeking reimbursement. Neither this resource nor Access Services by Bayer™ is intended as legal advice or as a substitute for a provider's independent professional judgment.

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Prior Authorization Tips

Many health plans and prescription drug plans require Prior Authorization for drugs used to treat cancer, which means that the prescriber or patient may need to obtain authorization before NUBEQA® (darolutamide) can be reimbursed. Prior authorization criteria can vary by plan, so it is recommended to contact the plan directly to verify that all required information is submitted.

Most plans will have a specific prior authorization request form to collect the required information. Provide complete and accurate information to avoid processing delays.

Here are some helpful tips to streamline the prior authorization process.

Include the following with every Prior Authorization request:

- Provider's ID number (not the facility ID number) so the plan can identify the prescriber
- ICD-10-CM diagnosis code that most closely describes the patient's diagnosis
- Name and National Drug Code (NDC) number for the drug

50419-395-01	NUBEQA® (darolutamide)	300 mg	Bottle of 120 tablets

- Completed prescription form
- Photocopy of the patient's insurance card
- Patient's authorization of information release

Plans may also require supporting documentation, such as laboratory test results and the patient's health history.

A letter of medical necessity may be required. If you need a sample letter of medical necessity, please contact your Bayer representative or download a template online at www.NUBEQAhcp.com

The provider's office should call to verify that the health plan received the faxed or mailed submission and follow-up with the plan if a determination is not received within five business days.

INDICATION

NUBEQA® (darolutamide) is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer.

IMPORTANT SAFETY INFORMATION

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.

Please see additional Important Safety Information on the next page.

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IMPORTANT SAFETY INFORMATION (continued)

Adverse Reactions

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 were urinary retention, pneumonia, and hematuria. Overall, 3.9% of patients receiving NUBEQA and 3.2% of patients receiving placebo died from adverse reactions, which included death (0.4%), cardiac failure (0.3%), cardiac arrest (0.2%), general physical health deterioration (0.2%), and pulmonary embolism (0.2%) for NUBEQA.

Adverse reactions occurring more frequently in the NUBEQA arm (≥2% over placebo) were fatigue (16% vs 11%), pain in extremity (6% vs 3%) and rash (3% vs 1%).

Clinically significant adverse reactions occurring in ≥2% of patients treated with NUBEQA included ischemic heart disease (4.0% vs 3.4% on placebo) and heart failure (2.1% vs 0.9% on placebo).

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 the previous page, and click here for the full Prescribing Information.

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MAC-NUB-US-0150-1 03/21