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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Sample Letter of Medical Necessity

The purpose of this sample letter of medical necessity or medical exception is to serve as a template if a patient's health plan has prescribing requirements or limitations for NUBEQA® (darolutamide), such as a prior authorization, step therapy or does not include NUBEQA on their formulary. In addition to a letter of medical necessity, health plans may also require the following items as supporting evidence:

- The patient's medical records, including any relevant lab and/or diagnostic results
- Clinical studies that support the choice of medication
- The Prescribing Information (PI) for the medication

Because each plan has its own medical exception process, the required information may vary, and additional supporting evidence may be required. Providing as much supporting information as possible may help with the health plan's timely consideration of your request.

The editable letter on the following page includes pink brackets that indicate variable fields that should be replaced with the relevant patient, physician, and office information. When submitting the letter, all brackets in the template should be removed and your office letterhead should be used.

This sample letter is offered as a model and is intended to be tailored according to the individual prescriber's and patient's needs.

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Sample Letter of Medical Necessity for NUBEQA® (darolutamide)

[DATE]
[HEALTH PLAN NAME]
[HEALTH PLAN CONTACT NAME]
[HEALTH PLAN MAILING ADDRESS]

Patient: [PATIENT FULL NAME]
Subscriber ID: [#XXXXXXXXXX]
[Subscriber Group ID: #XXXXXXXXXXXX]

Re: Request for NUBEQA® (darolutamide)

Dear [NAME OF CONTACT AT PAYER],

I am writing on behalf of my patient, [NAME OF PATIENT], to request that [PAYER COMPANY NAME] approve coverage for NUBEQA. [INDICATION].

This letter documents the medical necessity for use of NUBEQA for my patient and provides information about [NAME OF PATIENT]'s medical history and treatment, relevant test results, and a copy of the NUBEQA Prescribing Information.

[NAME OF PATIENT] is [a/an] [AGE]-year-old [male/female] with a diagnosis of [PATIENT DIAGNOSIS] as of [DATE OF DIAGNOSIS]. [NAME OF PATIENT] has been in my care for [PATIENT DIAGNOSIS] since [DATE]. [Provide a brief discussion of patient's relevant medical history, condition/symptoms, diagnostic test results, and therapy to date, including other treatments attempted and results].

Based on the above information, NUBEQA is indicated and medically necessary for [NAME OF PATIENT]'s treatment. If you have any questions, please contact me at [PHYSICIAN TELEPHONE NUMBER].

Thank you in advance for your immediate attention to this request.

Sincerely,

[PRESCRIBER NAME AND SIGNATURE]

Attachments: [ORIGINAL CLAIM FORM, COPY OF DENIAL OR EXPLANATION OF BENEFITS (IF APPLICABLE), COPY OF PATIENT'S INSURANCE CARD, NUBEQA PRESCRIBING INFORMATION, FDA APPROVAL LETTER, DAROLUTAMIDE PRIMARY PUBLICATION, ETC.]