



Patient Support Program Resources



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.





Navigating the Appeal Process

It is possible that a prescription for NUBEQA® (darolutamide) may be rejected or denied as not covered by the patient's health plan. In this case, a general process can be followed to appeal this denial.

What may be required as part of the appeal process?

Supporting documents are vital for the appeal process. These documents may include:

- Letter of medical necessity
 - o If you need a sample letter of medical necessity, please contact your Bayer representative or download a template online at www.NUBEQAhcp.com
- Photocopies of the patient's health plan and/or prescription cards
- Copies of the denial letter, benefits information, and the original claim/prescription request
- A letter of appeal
- Additional supporting documentation such as
 - o NUBEQA Prescribing Information, and relevant published clinical studies (such as data from the ARAMIS trial)
 - o Relevant laboratory and/or diagnostic information
 - o The patient's recent (6 months to a year) medical history

Because each plan has its own appeals process, the required information may vary, and additional supporting evidence or rationale may be required.

Helpful appeal process hints

- Photocopy all documents that are being submitted, as well as any formal correspondence with the health plan
- The patient's benefit information should be verified to ensure that the appeal request is valid
- Appeal guidelines vary from plan to plan and need to be tracked. Plan-specific items may include a deadline for the appeal, a submission fax number or mailing address that is specifically used for appeal or similar requests, how many times an appeal may be submitted, and if the patient or the physician is required to submit the appeal
- Appeal departments for health plans generally have readily available contact information, with individuals who can answer any questions that you or your office may have as it relates to the appeal process





• Verification of submission should be obtained. Receipt of faxed submissions can be verified with a follow-up phone call shortly after submission, and mailed submissions can be sent with tracking information, with a scheduled verification phone call 2 to 3 business days after the package is delivered

Sample Appeal Letter

A sample appeal letter is included on the following page. Providing as much supporting information as possible may help with the health plan's timely consideration for your request. The list on the previous page can be used to verify that all relevant, available information is being submitted along with the appeal.

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 the office letterhead should be used.

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



Sample Letter of Appeal 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: #XXXXXXXXXXXXXXXXXXX

Re: Appeal Request for NUBEQA® (darolutamide)

Dear [NAME OF CONTACT AT PAYER],

I am requesting an appeal for the medical necessity of NUBEQA for [NAME OF PATIENT] on [DATES OF SERVICE]. [PAYER COMPANY NAME] denied a claim due to [summarize insurer's stated reason for claim denial].

[INDICATION].

[NAME OF PATIENT] has been diagnosed with [PATIENT DIAGNOSIS] as of [DATE OF DIAGNOSIS], and [PROVIDE PATIENT'S RELEVANT MEDICAL HISTORY, CONDITION/SYMPTOMS, DIAGNOSTIC TEST RESULTS, AND THERAPY TO DATE, INCLUDING OTHER TREATMENTS ATTEMPTED AND RESULTS]. I believe NUBEQA is medically necessary and clinically appropriate for [NAME OF PATIENT].

Thank you in advance for your review and consideration for coverage. If you have any questions or require additional information regarding this patient, please contact me at [PHYSICIAN TELEPHONE NUMBER].

Sincerely, [PRESCRIBER NAME AND SIGNATURE]

Please find attached: [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.]