



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAROLUTAMIDE

Generic	Brand	HICL	GCN	Exception/Other
DAROLUTAMIDE	NUBEQA	45909		

GUIDELINES FOR USE

INITIAL CRITERIA (NOTE: FOR RENEWAL CRITERIA SEE BELOW)

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC) **AND** meet the following criterion?
 - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

If yes, continue to #2.

If no, do not approve.

DENIAL TEXT: See the denial text at the end of the guideline.

2. Has the patient previously received a bilateral orchiectomy?

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, continue to #3.

3. Is the requested medication being used concurrently with a gonadotropin releasing hormone (GnRH) agonist or antagonist (i.e., leuprolide, goserelin, histrelin, degarelix)?

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, do not approve.

INITIAL DENIAL TEXT: The guideline named **DAROLUTAMIDE (Nubeqa)** requires a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC). In addition, the following criteria must be met:

- The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)
- The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) agonist or antagonist (i.e., leuprolide, goserelin, histrelin, degarelix) **OR** the patient has previously received a bilateral orchiectomy

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DAROLUTAMIDE

GUIDELINES FOR USE (CONTINUED)

RENEWAL CRITERIA

1. Does the patient have a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC)?

If yes, **approve for 12 months by HICL with a quantity limit of #4 per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: The guideline named **DAROLUTAMIDE (Nubeqa)** requires a diagnosis of non-metastatic castration resistant prostate cancer (nmCRPC).

RATIONALE

For further information, please refer to the Prescribing Information and/or Drug Monograph for Nubeqa.

REFERENCES

- Nubeqa [Prescribing Information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/20

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P&T Approval: 10/19