



STANDARD COMMERCIAL DRUG FORMULARY
PRIOR AUTHORIZATION GUIDELINES

DAROLUTAMIDE

Generic	Brand	HICL	GCN	Medi-Span	Exception/Other
DAROLUTAMIDE	NUBEQA	45909		GPI-10 (2140242500)	

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 **ALL** of the following criteria?
 - The patient is 18 years of age or older
 - The patient has high risk prostate cancer (i.e., rapidly increasing prostate specific antigen [PSA] levels)

If yes, continue to #3.
If no, continue to #2.

2. Does the patient have a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) **AND** meet the following criterion?

- The requested medication will be used in combination with docetaxel

If yes, continue to #3.
If no, do not approve.

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

3. Does the patient meet **ONE** of the following criteria?
 - The patient previously received a bilateral orchiectomy
 - The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
 - The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**
If no, do not approve.

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

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INITIAL CRITERIA (CONTINUED)

INITIAL DENIAL TEXT: *Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for approval:

- A. You have ONE of the following diagnoses:
 - 1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
 - 2. Metastatic hormone-sensitive prostate cancer (mHSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)
- B. You meet ONE of the following:
 - 1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
 - 2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
 - 3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)
- C. **If you have non-metastatic castration resistant prostate cancer, approval also requires:**
 - 1. You are 18 years of age or older
 - 2. You have high risk prostate cancer (rapidly increasing prostate specific antigen [PSA: lab result that may indicate prostate cancer] levels)
- D. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**
 - 1. The requested medication will be used in combination with docetaxel

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

RENEWAL CRITERIA

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

If yes, continue to #3.

If no, continue to #2.

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RENEWAL CRITERIA (CONTINUED)

2. Does the patient have a diagnosis of metastatic hormone-sensitive prostate cancer (mHSPC) **AND** meet the following criterion?

- The requested medication will be used in combination with docetaxel

If yes, continue to #3.

If no, do not approve.

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

3. Does the patient meet **ONE** of the following criteria?

- The patient previously received a bilateral orchiectomy
- The patient has a castrate level of testosterone (i.e., < 50 ng/dL)
- The requested medication will be used concurrently with a gonadotropin releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, histrelin, degarelix)

If yes, **approve for 12 months by HICL or GPI-10 with a quantity limit of #4 per day.**

If no, do not approve.

RENEWAL DENIAL TEXT: ***Some terms are already pre-defined in parenthesis. Please use these definitions if the particular text you need to use does not already have definition(s) in it.**

Our guideline named **DAROLUTAMIDE (Nubeqa)** requires the following rule(s) be met for renewal:

A. You have ONE of the following diagnoses:

1. Non-metastatic castration resistant prostate cancer (nmCRPC: prostate cancer that has not spread to other parts of the body and does not respond to hormone therapy)
2. Metastatic hormone-sensitive prostate cancer (mHSPC: prostate cancer that has spread to other parts of the body and responds to hormone therapy)

B. You meet ONE of the following:

1. You previously received a bilateral orchiectomy (both testicles have been surgically removed)
2. You have a castrate level of testosterone (your blood testosterone levels are less than 50 ng/dL)
3. The requested medication will be used together with a gonadotropin releasing hormone analog (such as leuprolide, goserelin, histrelin, degarelix)

C. **If you have metastatic hormone-sensitive prostate cancer, approval also requires:**

1. The requested medication will be used in combination with docetaxel

Your doctor told us **[INSERT PT SPECIFIC INFO PROVIDED]**. We do not have information showing you **[INSERT UNMET CRITERIA]**. This is why your request is denied. Please work with your doctor to use a different medication or get us more information if it will allow us to approve this request.

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DAROLUTAMIDE

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.; August 2022.

Library	Commercial	NSA
Yes	Yes	No

Part D Effective: N/A

Commercial Effective: 01/01/23

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P&T Approval: 10/22