

**Nubeqa (darolutamide)**  
**Effective 07/01/2020**

<b>Plan</b>	<input checked="" type="checkbox"/> MassHealth <input checked="" type="checkbox"/> Commercial/Exchange	<b>Program Type</b>	<input checked="" type="checkbox"/> Prior Authorization <input checked="" type="checkbox"/> Quantity Limit <input type="checkbox"/> Step Therapy
<b>Benefit</b>	<input checked="" type="checkbox"/> Pharmacy Benefit <input type="checkbox"/> Medical Benefit (NLX)		
<b>Specialty Limitations</b>	This medication has been designated specialty and must be filled at a contracted specialty pharmacy.		
<b>Contact Information</b>	<b>Specialty Medications</b>		
	All Plans	Phone: 866-814-5506	Fax: 866-249-6155
	<b>Non-Specialty Medications</b>		
	MassHealth	Phone: 877-433-7643	Fax: 866-255-7569
	Commercial	Phone: 800-294-5979	Fax: 888-836-0730
	Exchange	Phone: 855-582-2022	Fax: 855-245-2134
	<b>Medical Specialty Medications (NLX)</b>		
	All Plans	Phone: 844-345-2803	Fax: 844-851-0882
<b>Exceptions</b>			

**Overview**

Darolutamide is a competitive androgen receptor inhibitor. In addition to androgen binding inhibition, darolutamide also inhibits androgen receptor translocation and androgen receptor-mediated transcription. Keto-darolutamide (active metabolite) has similar in vitro activity to darolutamide. Androgen receptor inhibition results in decreased proliferation of prostate tumor cells and increased apoptosis, leading to a decrease in tumor volume.

**Coverage Guidelines**

Authorization may be granted for members who are currently receiving treatment with Nubeqa, excluding when the product is obtained as samples or via manufacturer’s patient assistance programs

**OR**

Authorization may be granted for members when all the following criteria are met, and documentation is provided:

1. The member has a diagnosis of non-metastatic castration resistant prostate cancer
2. The provider specialty is oncologist or urologist, or medication is being prescribed in in consultation with an oncologist or urologist.
3. The member meets ONE of the following:
  - a. Medication is being used in combination a gonadotropin-releasing hormone analog (GnRH)
  - b. Member had had a bilateral orchiectomy

**Continuation of Therapy**

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.



### Limitations

1. Initial approvals will be granted for 12 months
2. The following quantity limits apply:

Nubeqa 300mg	120 tablets per 30 days
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### References

1. Nubeqa (darolutamide) [prescribing information]. Whippany, NJ: Bayer HealthCare Pharmaceuticals Inc.; July 2019.

### Review History

05/20/2020 – Created and Reviewed P&T Mtg. Effective 7/1/20

### Disclaimer

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