# Nubeqa (darolutamide)

**Effective 07/01/2020**

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

References

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

Disclaimer
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