Nubeqa

**Description**

Nubeqa (darolutamide)

**Background**

Nubeqa (darolutamide) is an androgen receptor (AR) inhibitor. Nubeqa competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. Nubeqa is thought to decrease prostate cancer cell proliferation and tumor volume in prostate cancer (1).

**Regulatory Status**

FDA approved indication: Nubeqa is an androgen receptor inhibitor indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (1).

Patients receiving Nubeqa should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy (1).

The safety and effectiveness of Nubeqa have not been established in females. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose of Nubeqa (1).

The safety and effectiveness of Nubeqa in pediatric patients less than 18 years of age have not been established (1).

**Related policies**

Erleada, Nilandron, Xtandi, Yonsa, Zytiga
Policy
This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Nubeqa may be considered **medically necessary** for patients 18 years of age or older for the treatment of Non-Metastatic Castration-Resistant Prostate Cancer (NM-CRPC) and if the conditions indicated below are met.

Nubeqa may be considered **investigational** in patients less than 18 years of age and for all other indications.

**Prior-Approval Requirements**

**Age**
18 years of age or older

**Gender**
Male

**Diagnoses**

Patient must have the following:

Non-Metastatic Castration-Resistant Prostate Cancer (NM-CRPC)

**AND ONE** of the following:
1. Patient is receiving gonadotropin-releasing hormone (GnRH) analog
2. Patient has had a bilateral orchiecotomy

**AND ALL** of the following:
1. **NO** dual therapy with another androgen receptor inhibitor (see Appendix 1)
2. Prescriber agrees to advise males with female partners of reproductive potential to use effective contraception during treatment and for 1 week after the last dose of Nubeqa

**Prior – Approval Renewal Requirements**
Same as above
### Policy Guidelines

#### Pre - PA Allowance

None

#### Prior - Approval Limits

<table>
<thead>
<tr>
<th>Quantity</th>
<th>360 tablets per 90 days</th>
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<tbody>
<tr>
<td>Duration</td>
<td>12 months</td>
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#### Prior – Approval Renewal Limits

Same as above

### Rationale

#### Summary

Nubeqa (darolutamide) is an androgen receptor (AR) inhibitor. Nubeqa competitively inhibits androgen binding, AR nuclear translocation, and AR-mediated transcription. Nubeqa is thought to decrease prostate cancer cell proliferation and tumor volume in prostate cancer. The safety and effectiveness of Nubeqa in pediatric patients less than 18 years of age have not been established (1).

Prior authorization is required to ensure the safe, clinically appropriate and cost effective use of Nubeqa while maintaining optimal therapeutic outcomes.

#### References


### Policy History

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
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<tbody>
<tr>
<td>August 2019</td>
<td>Addition to PA</td>
</tr>
<tr>
<td>September 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>December 2019</td>
<td>Annual review</td>
</tr>
<tr>
<td>Section:</td>
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<td>Subsection:</td>
<td>Antineoplastic Agents</td>
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<td>Subject:</td>
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This policy was approved by the FEP® Pharmacy and Medical Policy Committee on December 6, 2019 and is effective on January 1, 2020.
Appendix 1 - List of Androgen Receptor Inhibitors

<table>
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<tr>
<th>Generic Name</th>
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<tr>
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<td>Yonsa</td>
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<tr>
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<td>Zytiga</td>
</tr>
<tr>
<td>apalutamide</td>
<td>Erleada</td>
</tr>
<tr>
<td>darolutamide</td>
<td>Nubeqa</td>
</tr>
<tr>
<td>enzalutamide</td>
<td>Xtandi</td>
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<td>nilutamide</td>
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