RXADVANCE
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Southborough, MA 01772

Clinical Policy Title:	darolutamide
Policy Number:	RxA.414
Drug(s) Applied:	Nubeqa®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

Darolutamide (Nubeqa®) is an androgen receptor inhibitor. It is indicated for the treatment of patients with non-metastatic castration-resistant prostate cancer (nmCRPC).

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Darolutamide (Nubeqa®)	nmCRPC	600 mg PO BID	1,200 mg/day

Dosage Forms

- Tablet: 300 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Prostate Cancer (must meet all):

1. Diagnosis of nmCRPC;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Member meets (a or b):
    a. Nubeqa® is prescribed (one of the following):
        i. Concurrently with gonadotropin-releasing hormone (GnRH) analog therapy (*see Appendix D*);*
        ii. As monotherapy;
    b. Member has undergone a bilateral orchiectomy;
    **Prior authorization may be required.*
5. Request meets one of the following (a or b):*

a. Dose does not exceed 1,200 mg (4 tablets) per day;
b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
**Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval Duration:
Commercial: 12 months
Medicaid/HIM: 12 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all):
1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Nubeqa® for nmCRPC and has received this medication for at least 30 days;
2. Member is responding positively to therapy with no evidence of metastases;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 1,200 mg (4 tablets) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).
   **Prescribed regimen must be FDA-approved or recommended by NCCN.*

Approval Duration:
Commercial: 12 months
Medicaid/HIM: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
CRPC: castration-resistant prostate cancer
NCCN: National Comprehensive Cancer Network
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
nm: non-metastatic
LHRH: luteinizing-hormone releasing- hormone

APPENDIX B: Therapeutic Alternatives
Not applicable

APPENDIX C: Contraindications/Boxed Warnings
None reported

APPENDIX D: General Information
CRPC is prostate cancer that progresses clinically, radiographically, or biochemically despite castrate levels of serum testosterone (< 50 ng/dL).
Examples of androgen deprivation therapy for non-metastatic, castration-naïve prostate cancer include:
- Orchiectomy (surgical castration)
- Luteinizing-hormone releasing-hormone (LHRH) agonist given with or without a first-generation anti-androgen:
  - LHRH agonists: Zoladex® (goserelin), Vantas® (histrelin), leuprolide (Lupron Depot® or Eligard®),

and Trelstar® (triptorelin)
- Anti-androgens: bicalutamide (Casodex®), flutamide, and nilutamide (Nilandron®)

- LHRH antagonist: Firmagon® (degarelix)

References

1. Nubeqa Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; July 2019. Available at https://www.nubeqa-us.com/. Accessed July 30, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed July 30, 2020.
3. National Comprehensive Cancer Network. Prostate Cancer Version 02.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 30, 2020.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Initial approval criteria I.A.4.a.ii added to include monotherapy prescribing method. 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. Approval duration was updated in initial approval as well as in continued therapy approval. 5. References were updated.	08/26/2020	09/14/2020