Clinical Policy Title:	darolutamide
Policy Number:	RxA.414
Drug(s) Applied:	Nubeqa®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
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 orally twice daily For severe renal and hepatic impairment recommended dose is 300 mg twice daily	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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 concurrently with gonadotropin-releasing hormone (GnRH) analog therapy (see Appendix D);*
   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: 12 months

II. Continued Therapy Approval

A. Prostate Cancer (must meet all):

1. Member is 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: 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

- Contraindication(s):
  - None reported.

- Boxed warning(s):
  - 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)

- Embryo-Fetal Toxicity: Nubeqa® can cause fetal harm and loss of pregnancy. Advise males with female partners of reproductive potential to use effective contraception.

References

1. Nubeqa Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; January 2021. Available at https://www.nubeqa-us.com/. Accessed June 03, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: www.nccn.org. Accessed June 03, 2021.
3. National Comprehensive Cancer Network. Prostate Cancer Version 02.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed June 03, 2021.

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
Policy was reviewed: 1. Dosing Information dosing regimen was updated to include "For severe renal and hepatic impairment recommended dose is 300 mg twice daily…" 2. Statement about provider sample ''The provision of provider samples does not guarantee coverage…" was added to Clinical Policy. 3. Initial Approval Criteria and Continue Therapy Approval Criteria were updated to remove HIM approval duration. 4. Continued Therapy Approval Criteria I.A.4 was updated to remove "as monotherapy…".Appendix C was updated to include "Contraindications…" and "Boxed Warning…" 5. Appendix D was updated to includeembryo fetal toxicity info, "Embryo-Fetal Toxicity: Nubeqa® can cause fetal harm..." 6. References were reviewed and updated.	06/03/2021	09/14/2021