Clinical Policy: Darolutamide (Nubeqa)

Reference Number: ERX.SPA.345
Effective Date: 12.01.19
Last Review Date: 11.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Darolutamide (Nubeqa®) is an androgen receptor inhibitor.

FDA Approved Indication(s)
Nubeqa is indicated for the treatment of patients with:
- Non-metastatic castration resistant prostate cancer (nmCRPC)
- Metastatic hormone-sensitive prostate cancer (mHSPC) in combination with docetaxel

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

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Nubeqa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Prostate Cancer (must meet all)**:**

1. Diagnosis of nmCRPC or mHSPC;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age ≥ 18 years;
4. Member will use a gonadotropin-releasing hormone (GnRH) analog concurrently or has had a bilateral orchiectomy
5. If request is for mHSPC, Nubeqa is prescribed in combination with docetaxel;
6. 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:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Prostate Cancer

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Nubeqa for nmCRPC or mHSPC and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
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 – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CRPC: castration-resistant prostate cancer
FDA: Food and Drug Administration
GnRH: gonadotropin-releasing hormone
LHRH: luteinizing-hormone releasing-hormone
NCCN: National Comprehensive Cancer Network
mHSPC: metastatic hormone-sensitive prostate cancer
nm: non-metastatic

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)

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
nmCRPC, mHSPC	600 mg PO BID	1,200 mg/day

VI. Product Availability

Tablet: 300 mg

VII. References

1. Nubeqa Prescribing Information. Whippany, NJ: Bayer HealthCare Pharmaceuticals, Inc.; August 2022. Available at https://www.nubeqa-us.com/. Accessed August 22, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed July 26, 2022.
3. National Comprehensive Cancer Network. Prostate Cancer Version 04.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 26, 2022.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	09.03.19	11.19
4Q 2020 annual review: no significant changes; references reviewed and updated.	07.08.20	11.20
4Q 2021 annual review: no significant changes; references reviewed and updated.	07.15.21	11.21
4Q 2022 annual review: RT4: added additional indication for mHSPC per updated prescribing information; references reviewed and updated.	08.22.22	11.22

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.