

Clinical Policy: Darolutamide (Nubeqa)

Reference Number: CP.PHAR.435

Effective Date: 09.03.19

Last Review Date: 11.19

Line of Business: Commercial, HIM, 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).

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.

It is the policy of health plans affiliated with Centene Corporation[®] 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;
2. Prescribed by or in consultation with an oncologist or urologist;
3. Age \geq 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:

Medicaid/HIM – 12 months

Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Prostate Cancer (must meet all):

1. Currently receiving medication via Centene benefit, 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:

Medicaid/HIM – 12 months

Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.

Approval duration: Duration of request or 6 months (whichever is less); or

2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid.

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 policies – CP.CPA.09 for commercial, HIM.PHAR.21 for health insurance marketplace, and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

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)

V. Dosage and Administration

| Indication | Dosing Regimen | Maximum Dose |
|------------|----------------|--------------|
| nmCRPC | 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.; July 2019. Available at <https://www.nubeqa-us.com/>. Accessed August 19, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at www.nccn.org. Accessed August 19, 2019.
3. National Comprehensive Cancer Network. Prostate Cancer Version 04.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed August 19, 2019.

| Reviews, Revisions, and Approvals | Date | P&T Approval Date |
|--|----------|-------------------|
| Policy created. | 09.03.19 | 11.19 |
| Finalized line of businesses on policy to include HIM per SDC and prior clinical guidance. | 12.03.19 | |

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. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical

practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. 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. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note:

For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the non-formulary policy; HIM.PA.103.

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