

Drug Policy:

Nubeqa™ (darolutamide)

POLICY NUMBER UM ONC_1363	SUBJECT Nubeqa™ (darolutamide)		DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 08/14/19, 12/11/19, 05/13/20, 07/08/20, 08/12/20, 08/11/21, 09/08/21	APPROVAL DATE September 8, 2021	EFFECTIVE DATE September 24, 2021	COMMITTEE APPROVAL DATES 08/14/19, 12/11/19, 05/13/20, 07/08/20, 08/12/20, 08/11/21, 09/08/21	
PRIMARY BUSINESS OWNER: UM		COMMITTEE/BOARD APPROVAL Utilization Management Committee		
URAC STANDARDS HUM 1	NCQA STANDARDS UM 2		ADDITIONAL AREAS OF IMPACT	
CMS REQUIREMENTS	STATE/FEDERAL REQUIREMENTS		APPLICABLE LINES OF BUSINESS Commercial, Exchange, Medicaid	

I. PURPOSE

To define and describe the accepted indications for Nubeqa (darolutamide) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century Health (NCH) is responsible for processing all medication requests from network ordering providers. Medications not authorized by NCH may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

II. INDICATIONS FOR USE/INCLUSION CRITERIA

A. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

1. When health plan Medicaid coverage provisions—including any applicable PDLs (Preferred Drug Lists)—conflict with the coverage provisions in this drug policy, health plan Medicaid coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)
2. When health plan Exchange coverage provisions-including any applicable PDLs (Preferred Drug Lists)-conflict with the coverage provisions in this drug policy, health plan Exchange coverage provisions take precedence per the [Preferred Drug Guidelines OR](#)

3. For Health Plans that utilize NCH UM Oncology Clinical Policies as the initial clinical criteria, the [Preferred Drug Guidelines](#) shall follow [NCH L1 Pathways](#) when applicable, otherwise shall follow NCH drug policies **AND**
4. Continuation requests of previously approved, non-preferred medication are not subject to this provision **AND**
5. When available, generic alternatives are preferred over brand-name drugs.

B. Prostate Cancer

1. Nubeqa (darolutamide) use is supported in members who meet all the following criteria:
 - a. Non-Metastatic Castration – Resistant Prostate cancer, (M0) disease, a PSA doubling time of 10 months or less, **AND** the absence of documented metastases to any site by conventional imaging (pelvic lymph nodes below aortic bifurcation < 2 cm are allowed), **AND**
 - b. Nubeqa (darolutamide) will be used in combination with an LHRH analog (ADT- Androgen Deprivation Therapy).

III. EXCLUSION CRITERIA

- A. Disease progression on or after treatment with Nubeqa (darolutamide) or another Androgen Receptor Signaling Inhibitor [e.g., Xtandi (enzalutamide) or Erleada (apalutamide)].
- B. History of metastatic disease at any time or presence of detectable metastases.
- C. Concurrent use with other Androgen Receptor Signaling Inhibitors [e.g., Xtandi (enzalutamide)] or CYP17 inhibitors [e.g., Zytiga (abiraterone)].
- D. Dosing exceeds single dose limit of Nubeqa (darolutamide) 600 mg.
- E. Treatment exceeds the maximum limit of 120 (300 mg) tablets/month.
- F. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

VI. ATTACHMENTS

- A. None

VII. REFERENCES

- A. Nubeqa prescribing information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ 2021.
- B. Clinical Pharmacology Elsevier Gold Standard 2021.
- C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2021.
- D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2021.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD 2021.