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	APPROVAL DATE August 12, 2020	EFFECTIVE DATE August 28, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 08/14/19, 12/11/19, 05/13/20, 07/08/20, 08/12/20	
PRIMARY BUSINESS OWNER: UM APPROVED BY: Dr. Andrew Hertler		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 All	

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

NOTE: For the treatment of non-metastatic castrate-resistant prostate cancer (M0 disease with no visible metastases on standard imaging and a PSA doubling time of ≤ 10 months), Nubeqa (darolutamide) is the preferred agent per NCH Policy & NCH Pathway.

1. Nubeqa (darolutamide) use is supported in members who meet all the following criteria:
   a. Non-Metastatic Castration – Resistant Prostate cancer, (M0) disease, with a baseline PSA level of at least 2 ng/ml, 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) 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 PI prescribing information. Bayer HealthCare Pharmaceuticals Inc. Whippany, NJ 2019.

B. Clinical Pharmacology Elsevier Gold Standard. 2020.

C. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.

D. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.

E. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.