Drug Policy:

Erleada™ (apalutamide)

POLICY NUMBER UM ONC_1333	**SUBJECT** Erleada™ (apalutamide)		**DEPT/PROGRAM** UM Dept	**PAGE 1 OF 3**
DATES COMMITTEE REVIEWED 03/14/18, 03/13/19, 12/11/19, 03/11/20, 07/08/20, 08/12/20	**APPROVAL DATE** August 12, 2020	**EFFECTIVE DATE** August 28, 2020	**COMMITTEE APPROVAL DATES** (latest version listed last) 03/14/18, 03/13/19, 12/11/19, 03/11/20, 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 Erleada (apalutamide) 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. Non-Metastatic Castration Resistant Prostate Cancer (M0 disease with no visible metastases on conventional imaging AND a PSA Doubling Time of ≤ 10 months):

   NOTE: Per NCH Policy, the preferred Androgen Receptor Signaling Inhibitor 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) is Nubeqa (darolutamide).

   a. Erleada (apalutamide) may be used in this setting, in combination with an LH-RH analog (ADT- Androgen Deprivation Therapy) if the member has an intolerance or a contraindication to Nubeqa (Darolutamide). *Please refer to UM ONC_1363 for Nubeqa (darolutamide) policy.*

2. Metastatic Castration-Sensitive Prostate Cancer (M1 disease, castration-sensitive):

   NOTE: Per NCH Policy & Pathway, the preferred Androgen Receptor Signaling Inhibitor, for metastatic castration-sensitive prostate cancer is generic abiraterone over Xtandi (enzalutamide) & Erleada (apalutamide). *Please refer to UM ONC_1208 for abiraterone policy.*

   a. Erleada (apalutamide) may be used in combination with an LH-RH analog (ADT-Androgen Deprivation Therapy) for members with castration-sensitive distant metastatic disease (M1, castration-sensitive) who experience disease progression on abiraterone, AND who have not been previously treated with Xtandi (enzalutamide) OR Erleada (apalutamide).

III. EXCLUSION CRITERIA

A. Erleada (apalutamide) is being used after disease progression with the same regimen or another Androgen Receptor Inhibitor [e.g. Xtandi (enzalutamide) or Nubeqa (darolutamide)].

B. Concurrent use with other antiandrogens or CYP17 inhibitors [e.g. Zytiga (abiraterone)].

C. Dosing exceeds single dose limit of Erleada (apalutamide) 240 mg.

D. Treatment exceeds the maximum limit of 120 (60 mg) tablets/month.

E. 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

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VII. REFERENCES

A. Erleada (apalutamide) PI prescribing information. Janssen Products, LP. Horsham, PA 19044 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.

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