POLICY NUMBER UM ONC_1228	SUBJECT Xtandi™ (enzalutamide)		DEPT/PROGRAM UM Dept.	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 11/07/12, 04/09/14, 12/01/15, 12/21/16, 10/31/17, 11/08/17, 09/21/18, 08/14/19, 12/11/19, 04/08/20, 07/08/20	APPROVAL DATE July 8, 2020	EFFECTIVE DATE July 31, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 11/07/12, 04/09/14, 12/01/15, 12/21/16, 10/31/17, 11/08/17, 09/21/18, 08/14/19, 12/11/19, 04/08/20, 07/08/20	
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 Xtandi (enzalutamide) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

New Century is responsible for processing all medication requests from network ordering providers. Medications not authorized by New Century 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

1. PREFERRED MEDICATION GUIDANCE FOR INITIAL REQUEST:

a. 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**

b. 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**

c. 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**

d. Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**

e. When available, generic alternatives are preferred over brand-name drugs.

2. Prostate Cancer

a. 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 agent 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).

i. Xtandi (enzalutamide) may be used in this setting, in combination with an LH-RH analog (ADT- Androgyn Deprivation Therapy) if the member has an intolerance or a contraindication to Nubeqa (darolutamide).

b. 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).

i. Xtandi (enzalutamide) 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).

c. Metastatic Castration-Resistant Prostate Cancer:

i. Xtandi (enzalutamide) may be used in combination with an LH-RH analog (ADT- Androgen Deprivation Therapy) for members with castration-resistant distant metastatic (M1) disease if not previously treated with Xtandi (enzalutamide).

III. EXCLUSION CRITERIA

1. Member has disease progression while taking Xtandi (enzalutamide), or a similar Androgen Receptor Signaling Inhibitor such as Erleada (apalutamide) **OR** Nubeqa (darolutamode)
2. Xtandi (enzalutamide) is being used concurrently with other anti-cancer therapy including abiraterone, cabazitaxel, docetaxel, or sipuleucel-T, apalutamide, or darolutamide
3. Dosing exceeds single dose limit of Xtandi (enzalutamide) of 160 mg.
4. Treatment with Xtandi (enzalutamide) exceeds the maximum limit of 120 (40 mg) capsules per month.
5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

III. MEDICATION MANAGEMENT

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

IV. APPROVAL AUTHORITY

1. Review – Utilization Management Department
2. Final Approval – Utilization Management Committee

V. ATTACHMENTS

None

VII. REFERENCES

1. Xtandi prescribing information. Astellas Pharmaceutical Inc. Northbrook IL 2019.
2. Clinical Pharmacology Elsevier Gold Standard. 2020.
3. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, Co. 2020.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium. 2020.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs. Bethesda, MD. 2020.