POLICY NUMBER UM ONC_1208	SUBJECT Zytiga™ or Yonsa™ (abiraterone acetate)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 02/08/12, 01/09/13, 01/08/14, 06/09/15, 06/08/16, 06/28/17, 07/27/17, 07/19/18, 06/12/19, 12/11/19, 04/08/20	APPROVAL DATE April 8, 2020	EFFECTIVE DATE April 24, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 02/08/12, 01/09/13, 01/08/14, 06/09/15, 06/08/16, 06/28/17, 07/27/17, 07/19/18, 06/12/19, 12/11/19, 04/08/20	
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 Zytiga or Yonsa (abiraterone acetate) 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: http://pathways.newcenturyhealth.com **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. **NOTES: The preferred agent, per NCH Policies and NCH Pathway, for metastatic castrate sensitive prostate cancer (M1 disease) is Abiraterone Acetate over Enzalutamide. Generic Abiraterone is preferred when available/possible.**

b. Abiraterone is NOT indicated for Castrate-Resistant NON-METASTATIC prostate cancer (M0 disease with no radiographically visible metastases).

c. Metastatic Castrate-Sensitive Prostate Cancer

i. The member has metastatic castrate-sensitive prostate cancer and Abiraterone Acetate is being used in combination with a corticosteroid and an LHRH analog (ADT- Androgen Deprivation Therapy).

d. Metastatic Castrate-Resistant Prostate Cancer

i. As a single agent with a corticosteroid and an LHRH analog (ADT-Androgen Deprivation Therapy) for castration-resistance distant metastatic (M1) disease (if abiraterone not previously received).

III. EXCLUSION CRITERIA

1. Abiraterone is NOT indicated for Castrate-Resistant NON-METASTATIC prostate cancer (M0 disease with no radiographically visible metastase.s)
2. Member has disease progression while taking Abiraterone Acetate or has not had a trial of generic Abiraterone first prior to using brand Zytiga or Yonsa.
3. Abiraterone Acetate is being used concurrently with other cytotoxic chemotherapy.
4. Dosing exceeds single dose limit of Zytiga 1000 mg or Yonsa 500 mg.
5. Do not exceed Zytiga 60 or Yonsa 30 (500 mg) tablets/month.
6. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT

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

V. APPROVAL AUTHORITY

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

VI. ATTACHMENTS

None

VII. REFERENCES

1. Zytiga prescribing information. Centocor Ortho Biotech Inc, Horsham, PA. 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.