Drug Policy:

Zytiga™ or Yonsa™ (abiraterone acetate)

POLICY NUMBER UM ONC_1208	**SUBJECT** Zytiga™ or Yonsa™ (abiraterone acetate)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 4**
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, 02/10/21, 11/15/21, 01/12/22, 05/11/22, 08/22/22, 03/08/23	**APPROVAL DATE** March 8, 2023	**EFFECTIVE DATE** March 31, 2023	**COMMITTEE APPROVAL DATES** 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, 02/10/21, 11/15/21, 01/12/22, 05/11/22, 08/22/22, 03/08/23	
PRIMARY BUSINESS OWNER: UM		**COMMITTEE/BOARD APPROVAL** Utilization Management Committee		
URAC STANDARDS HUM v8: UM 1-2; UM 2-1	**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 Zytiga or Yonsa (abiraterone acetate) 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. Continuation requests for a not-approvable medication shall be exempt from this NCH policy provided:

1. The requested medication was used within the last year, AND

2. The member has not experienced disease progression and/or no intolerance to the requested medication, AND
3. Additional medication(s) are not being added to the continuation request.

B. Prostate Cancer

1. Abiraterone + corticosteroid + ADT (Androgen Deprivation Therapy) may be used in members with ANY of the following clinical situations:
    a. High Risk localized/non-metastatic prostate cancer (High Risk determination left to member's clinician)
    b. Metastatic castrate sensitive prostate cancer
    c. Metastatic castrate resistant prostate cancer
    d. Non-metastatic castrate resistant prostate cancer (defined by a rising PSA level with or without PSA doubling times of less than 10 months, in members with a baseline PSA greater than 2 ng/ml and castrate levels of testosterone is less than 50 ng/dl).
2. NOTE: Per NCH policy, Brand Zytiga/Yonsa is not approvable for prostate cancer. Brand Zytiga/Yonsa would be Approvable for use in prostate cancer if the member has an intolerance/contraindication to generic abiraterone. This recommendation is based on the lack of Level 1 evidence (randomized trials and or meta-analyses) to show that generic abiraterone (at any dose) is inferior to Brand Zytiga/Yonsa. Please refer to NCH alternative agents/regimens recommended by NCH, including but not limited to regimens available at http://pathways.newcenturyhealth.com.

III. EXCLUSION CRITERIA

A. 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.

B. Abiraterone Acetate is being used concurrently with other cytotoxic chemotherapy.

C. Dosing exceeds single dose limit and daily maximum dose of Zytiga (abiraterone acetate) 1000 mg or Yonsa 500 mg.

D. Do not exceed Zytiga (abiraterone acetate) 120 (250 mg) or 60 (500 mg); Yonsa 120 (125 mg) tablets/month.

E. Investigational use of Zytiga or Yonsa (abiraterone acetate) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
    1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definitions of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
    4. Whether the experimental design, considering the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it

may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).

5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

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

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H. Zytiga prescribing information. Centocor Ortho Biotech Inc, Horsham, PA. 2021.

I. Yonsa prescribing information. Sun Pharmaceutical Industries, Inc. Cranbury, NJ 2021.

J. Clinical Pharmacology Elsevier Gold Standard 2023.

K. Micromedex® Healthcare Series: Micromedex Drugdex Ann Arbor, Michigan 2023.

L. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2023.

M. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2023.

N. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. J Clin Oncol. 2014 Apr 20;32(12):1277-80.

O. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf.

P. NCQA UM 2023 Standards and Elements.