Drug Policy:

Zejula™ (niraparib)

POLICY NUMBER UM ONC_1307	**SUBJECT** Zejula™ (niraparib)		**DEPT/PROGRAM** UM Dept	**PAGE 1 of 4**
DATES COMMITTEE REVIEWED 04/05/17, 04/11/18, 04/10/19, 12/11/19, 03/11/20, 06/10/20, 05/12/21, 11/15/21, 03/09/22, 05/11/22, 09/14/22, 10/12/22, 11/09/22, 01/11/23, 03/08/23	**APPROVAL DATE** March 8, 2023	**EFFECTIVE DATE** March 31, 2023	**COMMITTEE APPROVAL DATES** 04/05/17, 04/11/18, 04/10/19, 12/11/19, 03/11/20, 06/10/20, 05/12/21, 11/15/21, 03/09/22, 05/11/22, 09/14/22, 10/12/22, 11/09/22, 01/11/23, 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 Zejula (niraparib) 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. Ovarian Cancer

1. Zejula (niraparib) may be used as monotherapy as follows:
    a. The member has newly diagnosed stage II-IV ovarian carcinoma and has undergone surgery (with or without optimal debulking) and has completed first line platinum-based chemotherapy AND Zejula (niraparib) is being used as a single agent maintenance therapy for members who are BRCA 1 or 2 mutation positive as confirmed by an FDA approved test OR
    b. The member has recurrent platinum-sensitive ovarian cancer and Zejula (niraparib) is being used as a single agent for maintenance therapy, after completion of platinum-based chemotherapy and the member is BRCA 1 or 2 mutation positive as confirmed by an FDA approved test).
2. NOTE: Per NCH Policy, the use of Zejula (niraparib) as monotherapy is not approvable for persistent disease or recurrence in members with/without deleterious germline BRCA 1 or 2 mutation who have been treated with two or more lines of chemotherapy. This Policy Position is based on the FDA withdrawal of Zejula (niraparib), totality of evidence, and ASCO guideline updates (see references below) showing a lack of OS benefit with PARP inhibitor therapy versus standard chemotherapy in the treatment of relapsed, BRCA-mutated, high-grade epithelial ovarian, fallopian tube or primary peritoneal cancer. 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. Zejula (niraparib) is being used in a member who experienced disease progression while receiving Zejula (niraparib) or disease progression while receiving another PARP inhibitor [e.g., Lynparza (Olaparib) or Rubraca (rucaparib)].

C. Use of Zejula (niraparib) not to exceed more than 1 line of maintenance therapy for recurrent ovarian cancer.

B. Lack of documentation for the detection of BRCA 1 or 2 mutation.

C. Dosing exceeds single dose limit of Zejula (niraparib) 300 mg.

D. Treatment exceeds the maximum limit of 90 (100 mg) tablets/month.

E. Use of Zejula (niraparib) not to exceed more than 1 line of maintenance therapy for recurrent ovarian cancer.

F. Investigational use of Zejula (niraparib) 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

A. GSK: Dear health care provider letter (niraparib): Important prescribing information. 2022. 2022. https://www.zejulahcp.com/content/dam/cf-pharma/hcp-zejulahcp-v2/en_US/pdf/ZEJULA%20(niraparib)%20Dear%20HCP%20Letter%20September%202022.pdf.

B. GSK: Dear health care provider letter (niraparib). Important drug warning. 2022. https://www.zejulahcp.com/content/dam/cf-pharma/hcp-zejulahcp-v2/en_US/pdf/ZEJULA%20(niraparib)%20Dear%20HCP%20Letter.pdf

C. Tew et al. ASCO Guidelines on PARP inhibitor use in Ovarian Cancer- Rapid Communication Update. DOI:https://doi.org/10.1200/JCO.22

D. González-Martín A, et al. PRIMA/ENGOT-OV26/GOG-3012 Clinical Trials. Niraparib in Patients with Newly Diagnosed Advanced Ovarian Cancer. N Engl J Med. 2019 Dec 19;381(25):2391-2402.

E. Fabbro M, et al. Efficacy and safety of niraparib as maintenance treatment in older patients (≥ 70 years) with recurrent ovarian cancer: Results from the ENGOT-OV16/NOVA trial. Gynecol Oncol. 2019 Mar;152(3):560-567.

F. Zejula prescribing information.GlaxoSmithKline Research Triangle Park, NC 2022.

G. Clinical Pharmacology Elsevier Gold Standard 2023.

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

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

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

K. 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.

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

M. NCQA UM 2023 Standards and Elements.