POLICY NUMBER UM ONC_1307	SUBJECT Zejula™ (niraparib)		DEPT/PROGRAM UM Dept	PAGE 1 OF 2
DATES COMMITTEE REVIEWED 04/05/17, 04/11/18, 04/10/19, 12/11/19, 03/11/20, 06/10/20	APPROVAL DATE June 10, 2020	EFFECTIVE DATE June 26, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 04/05/17, 04/11/18, 04/10/19, 12/11/19, 03/11/20, 06/10/20	
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 Zejula (niraparib) 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 dug alternatives are preferred over Brand name drugs.
2. **Ovarian Cancer**
    a. Niraparib is being used in ANY one of the following:
        i. The member has newly diagnosed stage III/IV ovarian carcinoma and has undergone surgery (with or without optimal debulking) and has completed first line platinum-based chemotherapy AND Niraparib is being used as a single agent for maintenance therapy (regardless of BRCA mutation test results). **NOTE: Niraparib is the Preferred agent per NCH Policy & NCH Pathway in this setting.**
        ii. The member has recurrent platinum-sensitive ovarian cancer and Niraparib is being used as a single agent for maintenance therapy, after completion of platinum-based

chemotherapy**. NOTE: Niraparib is the Preferred agent per NCH Policy & NCH Pathway in this setting.**

iii. The member has recurrent ovarian cancer (regardless of platinum sensitivity) and has had 3 or more prior lines of therapy and Niraparib is being used as a single agent.

III. EXCLUSION CRITERIA

1. Zejula (niraparib) is being used in a member who experienced disease progression while receiving Zejula (niraparib) or disease progression while receiving another PARP inhibitor (i.e. olaparib or rucaparib).
2. Concurrent use with other anti-cancer therapy.
3. Dosing exceeds single dose limit of Zejula (niraparib) 300 mg.
4. Treatment exceeds the maximum limit of 90 (100 mg) tablets/month.
5. 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. Zejula PI prescribing information. Genentech, Inc. South San Francisco, CA 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.