

POLICY NUMBER UM ONC_1273	SUBJECT Lynparza™ (olaparib)	DEPT/PROGRAM UM Dept	PAGE 1 OF 3
DATES COMMITTEE REVIEWED 03/27/15, 05/24/16, 06/29/17, 07/26/17, 07/19/18, 06/12/19, 12/11/19, 03/11/20, 07/08/20	APPROVAL DATE July 8, 2020	EFFECTIVE DATE July 31, 2020	COMMITTEE APPROVAL DATES (latest version listed last) 03/27/15, 05/24/16, 06/29/17, 07/26/17, 07/19/18, 06/12/19, 12/11/19, 03/11/20, 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 Lynparza (olaparib capsule or tablet) 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:

- 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**
- 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**
- 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**
- Continuation requests of previously approved non-preferred medication are not subject to this provision **AND**
- When available, generic drug alternatives are preferred over Brand name drugs.

2. Ovarian Cancer

NOTE: The Preferred PARP inhibitor, per NCH Policies and NCH Pathways, for maintenance therapy-either first line or after a platinum-sensitive relapse-in ovarian cancer is Zejula (niraparib).

NOTE: Per NCH Policy and NCH Pathway, the combination of Lynparza (olaparib) and Avastin (bevacizumab) for maintenance therapy of advanced ovarian cancer, is a non-preferred regimen. The preferred regimen in the above setting in single agent Zejula (niraparib).



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- a. Lynparza (olaparib tablet) may be used as single agent for **ANY** of the following:
 - i. First line maintenance therapy: For members with stage III/IV ovarian cancer with a deleterious/suspected deleterious germline BRCA 1/2 mutation, who have completed platinum-based chemotherapy, and Lynparza is being given as a single agent in the maintenance setting.
 - ii. For members with recurrent/metastatic ovarian cancer with a deleterious/suspected deleterious germline BRCA 1/2 mutation, who have completed platinum-based therapy for platinum-sensitive relapse.
 - iii. Members with recurrent/metastatic ovarian cancer, with a deleterious/suspected deleterious germline BRCA mutation, who have disease progression after 3 or more lines of prior therapy.

3. Breast Cancer

- a. Member is positive for a deleterious/suspected deleterious germline BRCA1/2 mutation and has metastatic/recurrent, regardless of HER2 and ER/PR-status **AND**
- b. Member has previously received chemotherapy in the neoadjuvant, adjuvant, or metastatic setting **AND**
- c. Member with hormone receptor-positive disease should have received prior endocrine therapy or be considered an inappropriate candidate for endocrine therapy.

4. Pancreas Adenocarcinoma

- a. Member has a deleterious/suspected deleterious germline BRCA 1/2 mutation and has metastatic pancreatic adenocarcinoma with stable/responding disease after platinum-based chemotherapy (including cisplatin + gemcitabine or an oxaliplatin-based regimen).

5. Prostate Cancer

NOTE: Lynparza (Olaparib) is only recommended in metastatic castration-resistant prostate cancer with germline/somatic BRCA1 or BRCA2 deleterious/suspected deleterious mutations.

- a. The member has metastatic castration-resistant prostate Cancer **AND**
- b. Tumor is positive for germline or somatic BRCA 1 or 2 based on an FDA approved companion diagnostic test (e.g. FoundationOne CDx or BRACAnalysis CDx) **AND**
- c. Member has disease progression on or after prior treatment with Zytiga (abiraterone) and/or Xtandi (enzalutamide) **AND**
- d. Lynparza (olaparib) will be used in combination with an LHRH analog (e.g. leuprolide) or as a single agent after bilateral orchiectomy.

III. EXCLUSION CRITERIA

- 1. Disease progression while taking Lynparza (olaparib) or another PARP inhibitor (i.e. niraparib or rucaparib).
- 2. Concurrent use with other chemotherapy.
- 3. Dosing exceeds single dose limit of Lynparza (olaparib) 400 mg (capsule) or 300 mg (tablet).
- 4. Treatment exceeds the maximum limit of 480 (50 mg) capsules/180 (100 mg) and 120 (150 mg) tablets per month.
- 5. Indications not supported by CMS recognized compendia or acceptable peer reviewed literature.

IV. MEDICATION MANAGEMENT



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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. Lynparza prescribing information. AstraZeneca Pharmaceuticals LP, Wilmington, DE. 2018.
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.