New Century Health

Drug Policy:

Lynparza™ (olaparib)

POLICY NUMBER UM ONC_1273	SUBJECT Lynparza™ (olaparib)		DEPT/PROGRAM UM Dept	PAGE 1 of 4
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, 05/12/21, 09/08/21, 11/15/21, 03/09/22, 05/11/22, 09/14/22 10/12/22, 11/09/22, 03/08/23, 05/10/23	APPROVAL DATE May 10, 2023	EFFECTIVE DATE May 26, 2023	COMMITTEE APPROVAL DATES 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, 05/12/21, 09/08/21, 11/15/21, 03/09/22, 05/11/22, 09/14/22, 10/12/22, 11/09/22, 03/08/23, 05/10/23	
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 Lynparza (olaparib) 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. Breast Cancer

1. Member is positive for a deleterious/suspected deleterious germline BRCA 1/2 mutation and has metastatic/recurrent breast cancer, regardless of HER-2 and ER/PR-status AND Lynparza (olaparib) will be used as monotherapy for the following:
    a. Member has previously received chemotherapy in the neoadjuvant, adjuvant, or metastatic setting AND
    b. Member with hormone receptor-positive disease should have received prior endocrine therapy or be considered an inappropriate candidate for endocrine therapy.
2. Lynparza (olaparib) may be use as adjuvant therapy for early stage (stages I-III)/non-metastatic HER-2 negative breast cancer if the member is positive for a germline BRCA 1 or BRCA 2 mutation. Such adjuvant therapy should be given after the completion of standard neoadjuvant/adjuvant chemotherapy and the duration of adjuvant Lynparza (olaparib) should not exceed 1 year in total.

C. Ovarian Cancer

1. Lynparza (olaparib) may be used, for members with stage II-IV ovarian cancer as follows:
    a. As a single agent maintenance therapy for members with a deleterious/suspected deleterious germline or somatic BRCA 1 or 2 mutation or homologous recombination deficiency positive (HRD positive), who have completed first line platinum-based chemotherapy without bevacizumab OR
    b. In combination with bevacizumab/bevacizumab biosimilar as 1st line maintenance therapy following response to primary chemotherapy with bevacizumab for members with any of the following: BRCA 1 or 2 mutation positive OR HRD positive (Homologous Recombination Deficiency positive) OR
    c. For use as maintenance therapy for members with recurrent/metastatic ovarian cancer with or without a deleterious/suspected deleterious germline/somatic BRCA 1 or 2 mutations, who have completed platinum-based therapy for platinum-sensitive relapse.
2. NOTE: The use of Lynparza (olaparib) as monotherapy is not supported by NCH Policy for persistent disease or recurrence in members with/without deleterious germline BRCA mutation who have been treated with two or more lines of chemotherapy. This policy position is based on the FDA withdrawal of Lynparza (olaparib) due to the findings from the SOLO3 study (see reference below) showing a lack of overall survival benefit with Lynparza (olaparib) monotherapy 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.

D. Pancreas Adenocarcinoma

1. Lynparza (olaparib) may be used as monotherapy in a member with a deleterious/suspected deleterious germline BRCA 1/2 mutation who has metastatic pancreatic adenocarcinoma with stable disease after 4-6 months of first line platinum-based chemotherapy (including cisplatin + gemcitabine or an oxaliplatin-based regimen).

E. Prostate Cancer

1. The member has metastatic castration-resistant prostate cancer AND
2. Tumor is positive for germline or somatic BRCA 1 or BRCA 2 mutation or is positive for another DNA Repair gene mutation/genomic aberration, as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx) AND
3. Member has disease progression on or after prior treatment with Zytiga (abiraterone) and/or Xtandi (enzalutamide) AND

4. 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

A. Disease progression while taking Lynparza (olaparib) or another PARP inhibitor [i.e.,Zejula (niraparib) or Rubraca (rucaparib)].

B. Use of Lynparza (olaparib) not to exceed more than 1 line of maintenance therapy for recurrent ovarian cancer.

C. Dosing exceeds single dose limit of Lynparza (olaparib) 300 mg.

D. Treatment exceeds the maximum limit of 180 (100 mg) and 120 (150 mg) tablets per month.

E. Investigational use of Lynparza (olaparib) 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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