Evolent Clinical Guideline 3193 for Lynparza™ (olaparib)

Guideline Number:	Applicable Codes	
Evolent_CG_3193		
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STATEMENT

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.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent 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.

INDICATIONS

Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided

- The member has not experienced disease progression on the requested medication AND
- The requested medication was used within the last year without a lapse of more than 30 days of having an active authorization AND
- Additional medication(s) are not being added to the continuation request.

Breast Cancer

- 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:
    - Member has previously received chemotherapy in the neoadjuvant, adjuvant, or metastatic setting AND
    - Member with hormone receptor-positive disease should have received prior endocrine therapy or be considered an inappropriate candidate for endocrine therapy.
- Lynparza (olaparib) may be used as a single agent 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.

Ovarian Cancer

- Lynparza (olaparib) may be used for members with stage II-IV ovarian cancer as follows:
    - 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

- 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
- 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.

- NOTE: The use of Lynparza (olaparib) as monotherapy is not supported by Evolent 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 Evolent alternative agents/regimens recommended by Evolent, including but not limited to regimens available at **Evolent Pathways**.

Pancreatic Cancer

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

Prostate Cancer

- The member has metastatic (M1) castration-resistant prostate cancer, and the 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
- Lynparza (olaparib) will be used in combination with Androgen Deprivation Therapy:
  - As monotherapy following disease progression with Zytiga (abiraterone) and/or Xtandi (enzalutamide) OR
  - In combination with abiraterone + prednisone (or prednisolone) for metastatic (M1) castration-resistant prostate cancer.

CONTRAINDICATIONS/WARNINGS

- None

EXCLUSION CRITERIA

- Disease progression while taking Lynparza (olaparib) or prior PARP inhibitor therapy [i.e., Zejula (niraparib) or Rubraca (rucaparib)].
- Lynparza (olaparib) is being used for metastatic castrate sensitive prostate cancer (mCSPC).
- Use of Lynparza (olaparib) exceeding more than 1 line of maintenance therapy for recurrent ovarian cancer.
- Dosing exceeds single dose limit of Lynparza (olaparib) 300 mg.
- Treatment exceeds the maximum limit of 120 (100 mg) and 120 (150 mg) tablets per month.
- 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:
    - Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
    - Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
    - 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.
    - 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).
    - 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.
    - That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
    - 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.Coding and Standards

Codes

- J8999 – olaparib

Applicable Lines of Business

☐	CHIP (Children's Health Insurance Program)
☒	Commercial
☒	Exchange/Marketplace
☒	Medicaid
☐	Medicare Advantage

POLICY HISTORY

Date	Summary
October 2025	• Converted to new Evolent guideline template • This guideline replaces UM ONC_1273 Lynparza (olaparib) • Updated indication section • Updated exclusion criteria • Updated maximum dosage form quantities in exclusion criteria • Updated references
October 2024	• Updated NCH verbiage to Evolent

LEGAL AND COMPLIANCE

Guideline Approval

Committee

Reviewed / Approved by Evolent Specialty Services Clinical Guideline Review Committee

Disclaimer

Evolent Clinical Guidelines do not constitute medical advice. Treating health care professionals are solely responsible for diagnosis, treatment, and medical advice. Evolent uses Clinical Guidelines in accordance with its contractual obligations to provide utilization management. Coverage for services varies for individual members according to the terms of their health care coverage or government program. Individual members' health care coverage may not utilize some Evolent Clinical Guidelines. Evolent clinical guidelines contain guidance that requires prior authorization and service limitations. A list of procedure

codes, services or drugs may not be all inclusive and does not imply that a service or drug is a covered or non-covered service or drug. Evolent reserves the right to review and update this Clinical Guideline in its sole discretion. Notice of any changes shall be provided as required by applicable provider agreements and laws or regulations. Members should contact their Plan customer service representative for specific coverage information.

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