

Applicable Drugs: Lynparza (olaparib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/20/2015

Date Last Reviewed / Revised: 12/12/2025

PRIOR AUTHORIZATION CRITERIA

(may be considered medically necessary when criteria I through V are met)

- I. Documented diagnosis of one of the following conditions A through D AND must meet criteria listed under applicable diagnosis:

FDA-Approved Indication(s)

A. Ovarian cancer

1. Documentation of advanced or recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer and meets the following:
 - i. Presence of deleterious or suspected deleterious germline or somatic BRCA-mutations and meets one of the following a or b:
 - a. Plan to use Lynparza as monotherapy
 - b. Homologous recombination deficiency (HRD)-positive status defined by a deleterious or suspected deleterious BRCA mutation or genomic instability AND used in combination with bevacizumab.
2. History of complete or partial response to first-line platinum-based chemotherapy.
3. The request is for maintenance treatment only.

B. Breast cancer

1. Documentation of one of the following i or ii:
 - i. High-risk early breast cancer with both of the following a and b:
 - a. Presence of deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) AND human epidermal growth factor receptor 2 (HER2)-negative.
 - b. Patient has been treated with neoadjuvant or adjuvant chemotherapy.
 - ii. Metastatic or recurrent breast cancer

- a. One of the following i or ii:
 - i. Patient is hormone receptor (HR)-negative.
 - ii. Patient is (HR)-positive AND disease progression with previous endocrine therapy or provider attestation that treatment with endocrine therapy is inappropriate.
- b. Documentation that patient has been previously treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.

C. Pancreatic cancer

- 1. Documentation of metastatic pancreatic adenocarcinoma.
- 2. Presence of deleterious or suspected deleterious gBRCAm.
- 3. Disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.
- 4. The request is for maintenance treatment only.

D. Prostate cancer

- 1. Documentation of metastatic castration-resistant prostate cancer (mCRPC)
- 2. Documentation of one of the following i or ii:
 - i. Presence of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations (ie, BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, RAD54L) AND disease progression despite prior treatment with enzalutamide or abiraterone.
 - ii. Presence of deleterious or suspected deleterious BRCA mutation AND used in combination with abiraterone AND prednisone or prednisolone.
- 3. Documentation of one of the following i or ii:
 - i. Used in combination with a gonadotropin-releasing hormone (GnRH) analog.
 - ii. History of bilateral orchiectomy.
- 4. Patient does not have PPP2R2A mutations.

Other Uses With Supportive Evidence

- E. Uterine Sarcoma/Leiomyosarcoma (LMS)
- F. Endometrial Carcinoma

II. Minimum age requirement: 18 years old.

III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.

- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.
- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- Request is for tablet formulation only.

QUANTITY / DAYS SUPPLY RESTRICTIONS

- 120 tablets per 30 days.

APPROVAL LENGTH

- **Authorization:** 6 months.
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

- N/A

REFERENCES

1. Lynparza. Prescribing information. AstraZeneca; 2025. December 12, 2025.
https://www.azpicentral.com/lynparza_tb/lynparza_tb.pdf#page=1
2. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Ovarian Cancer. Version 3.2025. Updated July 16, 2025. Accessed December 12, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf
3. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Breast Cancer. Version 5.2025. Updated October 16, 2025. Accessed December 12, 2025.
https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
4. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Pancreatic Adenocarcinoma. Version 2.2025. Updated February 3, 2025. Accessed December 12, 2025. https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf

5. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Prostate Cancer. Version 4.2026. Updated December 4, 2025. Accessed December 12, 2025. https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
6. National Comprehensive Cancer Network (NCCN). Clinical Practice Guidelines in Oncology. Uterine Neoplasms. Version 2.2026. Updated November 14, 2025. Accessed December 12, 2025. https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.