Generic Name: Olaparib

Therapeutic Class or Brand Name: Lynparza®

Applicable Drugs (if Therapeutic Class): N/A

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/20/2015

Date Last Reviewed / Revised: 11/18/2024

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 E 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 one of the following i or ii:
   a. Presence of deleterious or suspected deleterious germline or somatic BRCA-mutations.
   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 a or b:
   a. High-risk early breast cancer
      i. Presence of deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) AND human growth factor receptor 2 (HER2)-negative.
      ii. One of the following i or ii:
         i. Patient is hormone receptor (HR)-negative.

ii. Patient is (HR)-positive AND continuing concurrent treatment with endocrine therapy AND previously treated with neoadjuvant or adjuvant chemotherapy.

b. Metastatic or recurrent breast cancer

i. Presence of deleterious or suspected deleterious gBRCAm AND human growth factor receptor 2 (HER2)-negative.

ii. One of the following i or ii:

i. Patient is hormone receptor (HR)-negative.

iii. Patient is (HR)-positive AND disease progression with previous endocrine therapy or provider attestation that treatment with endocrine therapy is inappropriate.

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:

a. 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.

b. 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:

a. Used in combination with a gonadotropin-releasing hormone (GnRH) analog.

b. History of bilateral orchiectomy.

4. Patient does not have PPP2R2A mutations.

Other Uses With Supportive Evidence

E. Uterine Sarcoma/Leiomyosarcoma (LMS)

1. Documentation of advanced, recurrent/metastatic, or inoperable disease.
2. Presence of BRCA mutation.
3. The request is for use as a single agent.
4. The request is for use as a second-line or subsequent therapy after at least 1 systemic regimen.

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 clinical practice guidelines.

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; 2023. Accessed November 2, 2024. https://www.azpicentral.com/lynparza_tb/lynparza_tb.pdf#page=1
2. National Comprehensive Cancer Network (NCCN). Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 3.2024. Updated July 15, 2024. Accessed

November 6, 2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

3. National Comprehensive Cancer Network (NCCN). Breast Cancer. Version 4.2024. Updated July 3, 2024. Accessed November 6, 2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
4. National Comprehensive Cancer Network (NCCN). Pancreatic Adenocarcinoma. Version 3.2024. Updated August 02, 2024. Accessed November 6, 2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf
5. National Comprehensive Cancer Network (NCCN). Prostate Cancer. Version 4.2024. Updated May 17, 2024. Accessed November 6, 2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
6. National Comprehensive Cancer Network (NCCN). Uterine Neoplasms. Version 3.2024. Updated September 20, 2024. Accessed October 31, 2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf