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: 11/17/2021

PRIOR AUTHORIZATION CRITERIA

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

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

A. Deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer as detected by an FDA-approved test AND criteria 1 through 3 are met:

1. Test results confirming the *BRCA*-mutation must be submitted.
2. Documentation that the patient is in complete or partial response to platinum-based chemotherapy.
3. Documentation that the patient will be on maintenance treatment only.

B. Advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer associated with homologous recombination deficiency (HRD)-positive status as detected by an FDA-approved test AND criteria 1 through 4 are met:

1. Test results confirming HRD positive status defined by BRCA-mutation or genomic instability must be submitted.
2. Documentation that the patient is in complete or partial response to platinum-based chemotherapy.
3. Documentation that Lynparza will be used in combination with bevacizumab.
4. Documentation that the patient will be on maintenance treatment only.

C. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer AND criteria 1 and 2 are met:

1. Documentation that patient is in a complete or partial response to platinum-based chemotherapy.
2. Documentation that the patient will be on maintenance treatment only.

D. Deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer as detected by an FDA-approved test AND criteria 1 and 2 are met:
    1. Test results confirming the *BRCA*-mutation must be submitted.
    2. Documentation that patient has been treated with three or more prior lines of chemotherapy.

E. Deleterious or suspected deleterious germline BRCA-mutated, HER2-negative metastatic breast cancer AND criteria 1 and 2 are met:
    1. Test results confirming *BRCA*-mutation and HER2-negative status must be submitted.
    2. For patients with HR-positive breast cancer, there must be documentation that the patient has been treated with prior endocrine therapy or be considered inappropriate for endocrine therapy.

F. Deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma AND criteria 1 and 2 are met:
    1. Documentation that disease has not progressed on at least 16 weeks of platinum-based chemotherapy.
    2. Documentation that the patient will be on maintenance treatment only.

G. Deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) as detected by an FDA-approved test AND criteria 1 through 3 are met:
    1. Test results confirming HRR gene mutations must be submitted.
    2. Patient does not have PPP2R2A mutations.
    3. Documentation that the disease has progressed following prior treatment with enzalutamide or abiraterone.

II. Minimum age requirement: 18 years old.

III. The prescribing physician is an oncologist.

EXCLUSION CRITERIA

- N/A

OTHER CRITERIA

- Request is for tablet formulation only. Capsule formulation cannot be substituted for tablet formulation.

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 that the medication is effective.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network (NCCN). Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 3.2021. Updated September 9, 2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf
2. National Comprehensive Cancer Network (NCCN). Breast Cancer. Version 8.2021. Updated September 13, 2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
3. National Comprehensive Cancer Network (NCCN). Pancreatic Adenocarcinoma. Version 2.2021. Updated February 25, 2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf
4. National Comprehensive Cancer Network (NCCN). Prostate Cancer. Version 1.2022. Updated September 10, 2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
5. Medi-Span®.
6. Lynparza® [Package Info]. Wilmington, DE: AstraZeneca; June 2021. Available at: https://www.azpicentral.com/lynparza_tb/lynparza_tb.pdf#page=1.