Generic Name: Olaparib

Therapeutic Class or Brand Name: Lynparza®

Applicable Drugs (if Therapeutic Class): N/A

GPI Code: 2153556000

Preferred: N/A

Non-preferred: N/A

Date of Origin: 1/20/2015

Date Last Reviewed / Revised: 1/22/2020

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 E AND must meet criteria listed under applicable diagnosis:
   A. 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.
   B. 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.
   C. 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.
   D. 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.

E. 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.

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 3.2019. Updated November 26, 2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf

2. National Comprehensive Cancer Network (NCCN). Breast Cancer. Version 1.2020. Updated January 15, 2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf
3. National Comprehensive Cancer Network (NCCN). Pancreatic Adenocarcinoma. Version 1.2020. Updated November 26, 2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf
4. Medi-Span®.
5. Lynparza® [Package Info]. Wilmington, DE: AstraZeneca; December 2019. Available at: http://www.azpicentral.com/Lynparza/pi_lynparza.pdf#page=1.

HISTORICAL TRACKING OF CHANGES MADE TO POLICY

Date	Notes/Changes
1/22/2020	1. **Added** "**I. C.** 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.", "**I. D.** 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.", "**I. E.** 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." **under Prior Authorization Criteria.** 2. **Removed** "I.B.3. Documentation that the patient will be using the tablets and NOT the capsules" **from Prior Authorization Criteria**. 3. **Added** "Request is for tablet formulation only. Capsule formulation cannot be substituted for tablet formulation." **under Other Criteria.** 4. **Removed** "448 capsules per 28 days" **from Quantity/Days Supply Restrictions**. 5. **Removed** "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/lynparza_umcriteria.pdf" **Added** "https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf", "https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf", "https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf" **under References**.
10/5/2018	1. **Deleted** reference #4 (duplicate of reference #3)
12/1/2017	1. **Changed** "I. I. Documented diagnosis of deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer as detected by an FDA-

	approved test (test results confirming the BRCA-mutation must be submitted); II. Documentation that member has been treated with three or more prior lines of chemotherapy" **to** "I. Documented diagnosis of one of the following conditions A through B AND must meet criteria listed under applicable diagnosis: A. 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; B. Recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer AND criteria 1 through 3 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; Documentation that the patient will be using the tablets and NOT the capsules" **under Prior Authorization**. 2. **Changed** "448 capsules per 28 days" **to** "448 capsules per 28 days OR 120 tablets per 30 days" **under Quantity/Days Supply Restrictions**. 3. **Updated** "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/Lynparza_criteria.pdf" **to** "http://www.bcbsnc.com/assets/services/public/pdfs/formulary/lynparza_umcriteria.pdf" **under References**. 4. **Added** "http://www.azpicentral.com/Lynparza/pi_lynparza.pdf#page=1" **under References**.
9/13/2016	1. Policy reviewed: no changes made.