VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Lynparza™ (olaparib capsules and tablets – AstraZeneca)

DATE REVIEWED: 01/15/2020; 05/27/2020 selected revision

OVERVIEW

Lynparza, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated for the following[1]:

1) In adult patients with deleterious or suspected deleterious germline BReast CAncer (g*BRCA*)-mutated advanced **ovarian cancer** who have been **treated** with three or more prior lines of chemotherapy.
2) Maintenance treatment of adult patients with **recurrent** epithelial **ovarian,** fallopian tube, or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy.
3) Maintenance treatment of adult patients with deleterious or suspected deleterious g*BRCA* or somatic *BRCA*-mutated advanced epithelial **ovarian,** fallopian tube, or primary peritoneal cancer who are in complete or partial response to **first-line** platinum-based chemotherapy.
4) Indicated in combination with bevacizumab for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either: **a)** a deleterious or suspected deleterious BRCA mutation, and/or **b)** genomic instability.
5) In patients with deleterious or suspected deleterious g*BRCA* mutated, HER2-negative metastatic **breast cancer**, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy.
6) Maintenance treatment of adult patients with deleterious or suspected deleterious gBRCA mutated metastatic **pancreatic adenocarcinoma** whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen.
7) For the treatment of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) who have progressed following prior treatment with Xtandi (enzalutamide tablets) or abiraterone.

Lynparza tablets and capsules are not interchangeable; they have different dosing and bioavailability. The tablet formulation yields a lower daily pill burden than the capsule formulation.

Guidelines

The National Comprehensive Cancer Network (NCCN) guidelines on ovarian cancer (version 3.2019 – November 26, 2019) recommend Lynparza for maintenance therapy after primary treatment in patients who have had a complete or partial response.[2] Lynparza is recommended for *BRCA* 1/2 mutations (category 1 for germline mutations; category 2A for somatic mutations). The guidelines recommend use of Zejula™ (niraparib capsules), Rubraca™ (rucaparib tablets), or Lynparza as maintenance therapy options in patients with platinum-sensitive disease who have completed two or more lines of platinum-based therapy. note that the therapy options for patients with recurrent disease are primarily dependent on whether the patient is considered *platinum-resistant* (patients who relapse < 6 months after initial platinum chemotherapy) or *platinum-sensitive* (patients who relapse ≥ 6 months after initial platinum chemotherapy). The guidelines recommend Lynparza as one of the preferred single-agent targeted therapies for patients with deleterious germline *BRCA* mutated advanced (persistent disease or recurrence) ovarian cancer-following three or more lines of therapy (category 2A).

The NCCN breast cancer guidelines (version 3.2019 – September 6, 2019) recommend Lynparza as one of the preferred single agents for HER2-negative, *BRCA* 1/2 positive tumors, in the recurrent or metastatic setting (category 1).[3]

The NCCN pancreatic adenocarcinoma guidelines (version 1.2020 – November 26, 2019) recommend Lynparza for maintenance therapy after the patient has tried first-line systemic therapy.[4] It is specifically recommended in patients who have germline *BRCA* 1/2 mutations and who have not had disease progression after at least 4 to 6 months of chemotherapy.

The NCCN prostate cancer guidelines (version 2.2020 – May 21, 2020) recommends Lynparza for HRRm in the second-line setting (category 1), after first-line treatment with Xtandi or abiraterone. In patients who have received first-line docetaxel, Lynparza is a category 2B recommended therapy in the second-line setting for HRRm. In a footnote it is noted that Lynparza is a treatment option for patients with mCRPC and a pathogenic mutation (germline and/or somatic) in a HRR gene (*BRCA1*, *BRCA2*, *ATM*, *BARD1*, *BRIP1*, *CDK12*, *CHEK1*, *CHEK2*, *FANCL*, *PALB2*, *RAD51B*, *RAD51C*, *RAD51D*, or *RAD54L)*, who have been treated with androgen receptor-directed therapy. Patients with PPP2R2A mutation in the PROfound trial experienced an unfavorable risk-benefit profile. Therefore, Lynparza is not recommended in patients with a PPP2R2A mutations.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Lynparza. All approvals are provided for 3 years in duration.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Lynparza is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Ovarian Cancer – Treatment.**
   - **A)** Initial Therapy. Approve for 3 years if the patient meets the following criteria (i and ii):
     - **i.** The patient has a germline *BRCA*-mutation as confirmed by an approved test; AND
     - **ii.** The patient has progressed on three or more prior lines of chemotherapy.
   - **B)** Patient is Currently Receiving Lynparza. Approve for 3 years if the patient has a *BRCA* mutation (germline) as confirmed by an approved test.

2. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance, Monotherapy.** Approve for 3 years if the patient meets one of the following criteria (A or B):
   - **A)** The patient meets both of the following criteria for first-line maintenance therapy (i and ii):
     - **i.** The patient has a germline or somatic *BRCA* mutation-positive disease as confirmed by an approved test; AND
     - **ii.** The patient is in complete or partial response to first-line platinum-based chemotherapy regimen (e.g., carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin); OR
   - **B)** The patient is in complete or partial response after at least two platinum-based chemotherapy regimens.

Note: Examples of platinum-based chemotherapy are carboplatin with gemcitabine, carboplatin with paclitaxel, cisplatin with gemcitabine.

3. **Ovarian, Fallopian Tube, or Primary Peritoneal Cancer – Maintenance, Combination Therapy.** Approve for 3 years if the patient meets one of the following criteria (A, B, and C):
   - **A)** The medication is used in combination with bevacizumab; AND
   - **B)** The patient has homologous recombination deficiency (HRD)-positive disease as confirmed by an approved test.
     Note: HRD-positive disease includes patients with *BRCA* mutation-positive disease; AND
   - **C)** The patient is in complete or partial response to first-line platinum-based chemotherapy regimen
     Note: Examples of chemotherapy regimens are carboplatin with paclitaxel, carboplatin with doxorubicin, docetaxel with carboplatin.

4. **Breast Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, C, and D):
   - **A)** The patient has metastatic, germline *BRCA* mutation-positive breast cancer; AND
   - **B)** The patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer; AND
   - **C)** The patient meets ONE of the following criteria (i or ii):
     - **i.** The patient meets BOTH of the following criteria (a and b):
       - **a)** The patient has hormone receptor positive (HR+) [i.e., estrogen receptor positive {ER+} and/or progesterone receptor positive {PR+}] disease; AND
       - **b)** The patient meets ONE of the following criteria (1 or 2):
         - **(1)** The patient has been treated with prior endocrine therapy; OR
         - **(2)** The patient is considered inappropriate for endocrine therapy; OR
     - **ii.** Patient has triple negative disease (i.e., ER-negative, PR-negative, and HER2-negative); AND
   - **D)** The patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting.

5. **Pancreatic Cancer – Maintenance Therapy.** Approve for 3 years if the patient meets the following criteria (A and B):
   - **A)** The patient has a germline *BRCA* mutation-positive metastatic disease; AND
   - **B)** The disease has not progressed on at least 16 weeks of treatment with a first-line platinum-based chemotherapy regimen.

6. **Prostate Cancer – Castration-Resistant.** Approve for 3 years if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** The patient has metastatic disease; AND
   - **B)** The patient meets one of the following criteria (i or ii):
     - **i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
       Note: Examples are Lupron (leuprolide for injection), Lupron Depot (leuprolide acetate for depot suspension), Trelstar (triptorelin pamoate for injectable suspension), Zoladex (goserelin acetate implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix for injection).
     - **ii.** The patient has had a bilateral orchiectomy; AND
   - **C)** The patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease, as confirmed by an approved test; AND
     Note: HRR gene mutations include *BRCA1*, *BRCA2*, *ATM*, *BARD1*, *BRIP1*, *CDK12*, *CHEK1*, *CHEK2*, *FANCL*, *PALB2*, *RAD51B*, *RAD51C*, *RAD51D*, or *RAD54L*.
   - **D)** The patient does not have a *PPP2R2A* mutation; AND
   - **E)** The patient has been previously treated with abiraterone or Xtandi (enzalutamide capsules).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Lynparza has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Lynparza™ capsules [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2020.
2. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (Version 3.2019 – November 26, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on. January 13, 2020.
3. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 3.2019 – September 6, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 13, 2020.
4. The NCCN Pancreatic Adenocarcinoma Clinical Practice Guidelines in Oncology (Version 1.2020 – November 26, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on January 13, 2020.
5. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (Version 2.2020 – May 21, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed May 23, 2020.