blue of california

olaparib tablet (LYNPARZA)

Diagnoses Considered for Coverage:

- Ovarian cancer
- Breast cancer
- Pancreatic cancer
- Prostate cancer
- Uterine leiomyosarcoma

Coverage Criteria:

For epithelial ovarian, fallopian tube, or primary peritoneal cancer:

- Being used for maintenance (prevention of recurrence), and
- Dose does not exceed 600 mg per day, and
- Patient has had partial or complete response to a platinum-based chemotherapy, AND

A. Following first-line chemotherapy:

- One of the following:
  i. Being used as single agent, **OR**
  ii. Being used in combination with bevacizumab,

OR

B. Following second-line or later chemotherapy:

- Being used as single agent.

For breast cancer:

- One of the following:
  i. Patient had no response to preoperative systemic therapy, or
  ii. Disease is recurrent, unresectable (local or regional) or metastatic breast cancer, **and**
- Presence of BRCA gene mutation, **and**
- Being used as a single agent, **and**
- Dose does not exceed 600 mg per day.

For pancreatic cancer:

- Being used for maintenance (prevention of recurrence) of pancreatic cancer, **and**
- Being used for metastatic disease, **and**
- Presence of BRCA (type 1 or 2) gene mutation positive disease, **and**
- Previous history of a platinum-based chemotherapy regimen, **and**
- Being used as a single agent, **and**
- Dose does not exceed 600 mg per day.

For prostate cancer:

- Being used for castration resistant metastatic disease, **and**
- Meets one of the following (a or b):
    - Being used as a single agent (in conjunction with androgen deprivation therapy, and both of the following:
        - Patient has homologous recombination repair (HRR) gene mutation positive disease (genes involved in HRR include ATM, BRCA1, BRCA2, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D, RAD54L), **AND**
        - Patient has previously received either enzalutamide (Xtandi) or abiraterone, **OR**
    - Being used in combination with abiraterone and prednisone or prednisolone, **AND**
        - Patient has BRCA gene mutation (BRCA1, BRCA2) positive disease.

  AND
- One of the following:
    - Being used with LHRH agonist or antagonist therapy [e.g. leuprolide (Lupron, Eligard), goserelin (Zoladex), triptorelin (Trelstar), degarelix (Firmagon)], OR
    - Patient has had bilateral orchiectomy,

  AND
- Dose does not exceed 600 mg per day.

2. **For uterine leiomyosarcoma:**
    - Being used for second-line or subsequent therapy, **and**
    - Being used as a single agent, **and**
    - Presence of type 2 BRCA gene mutation, **and**
    - Dose does not exceed 800 mg per day.

Coverage Duration: one year

Effective Date: 08/30/2023