Commercial/Healthcare Exchange PA Criteria

Effective: November 2, 2016

Products Affected: Lynparza (olaparib) oral capsules

Medication Description:

Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as monotherapy in patients with deleterious or suspected deleterious germline BRCA-mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. The BRCA mutation is required to be detected by a Food and Drug Administration (FDA)-approved test.

The indication was approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Lynparza is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1, PARP2, and PARP3. PARP enzymes are involved in normal cellular homeostasis such as DNA transcription, cell cycle regulation, and DNA repair. Lynparza has been shown to inhibit growth of select tumor cell lines in vitro and decrease tumor growth in mouse xenograft models of human cancer both as monotherapy or following platinum-based chemotherapy. Increased cytotoxicity and anti-tumor activity following treatment with Lynparza were noted in cell lines and mouse tumor models with deficiencies in BRCA. In vitro studies have shown that Lynparza-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARM-DNA complex, resulting in disruption of cellular homeostasis and cell death.

Covered Uses:

1. BRCA-mutated Advanced epithelial ovarian, fallopian tube or primary peritoneal cancer (maintenance treatment)
2. Advanced epithelial ovarian, fallopian tube or primary peritoneal cancer (maintenance treatment)
3. Recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (maintenance treatment)
4. Advanced ovarian cancer
5. Metastatic Breast Cancer
6. Pancreatic Adenocarcinoma (maintenance treatment)
7. Metastatic castration-resistant prostate cancer

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. BRCA mutations as detected by an FDA-approved test
3. HER-2 status
4. Previous therapies tried

Age Restrictions: 18 years of age or older

Prescriber Restrictions: Prescribed by, or in consultation with, an Oncologist

Coverage Duration: 3 years

Other Criteria:

BRCA-mutated Advanced epithelial ovarian, fallopian tube or primary peritoneal cancer (maintenance treatment)

A. Patient has a diagnosis of deleterious or suspected deleterious germline or somatic BRCA-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer; AND
B. Patient is in complete or partial response to first-line platinum-based chemotherapy.

Advanced epithelial ovarian, fallopian tube or primary peritoneal cancer (maintenance treatment)

A. Patient is in complete or partial response to first-line platinum-based chemotherapy; AND
B. Patient's cancer is associated with homologous recombination deficiency (HRD) positive status defined by one of the following:
    a. a deleterious or suspected deleterious BRCA mutation, OR
    b. genomic instability; AND
C. Patient is using in combination with Bevacizumab

Recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (maintenance treatment)

A. Patient has a diagnosis of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer; AND
B. Patient is in complete or partial response to platinum-based chemotherapy.

Advanced ovarian cancer

A. Patient has a diagnosis of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer; AND
B. Patient has been previously treated with three or more prior lines of chemotherapy.

Metastatic Breast Cancer

A. Patient has a diagnosis of deleterious or suspected deleterious germline BRCA-mutated, HER2- negative metastatic breast cancer; AND
B. Patient has been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting; AND
C. Patients with hormone receptor positive breast cancer have documentation of one of the following:
    a. Patient has previous treatment with an endocrine therapy; OR
    b. Patient is considered inappropriate for endocrine therapy

Pancreatic Adenocarcinoma (maintenance treatment)

A. Patient has documented diagnosis of deleterious or suspected deleterious germline BRCA-mutated metastatic pancreatic adenocarcinoma; AND
B. Patient's disease has not progressed on at least 16 weeks of first line platinum-based chemotherapy regimen.

Metastatic castration-resistant prostate cancer

A. Patient has a diagnosis of adult patients with deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC); AND
B. Patient has progressed following prior treatment with enzalutamide or abiraterone.

References:

1. Lynparza [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; August 2016.
2. The NCCN Ovarian Cancer Clinical Practice Guidelines in Oncology (Version 1.2016). © 2015 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on August 23, 2016.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	Moved to new template – updated indications to match FDA label Removed Lynparza from CCI oncology policy	All	5/20/2020