BlueCross BlueShield Federal Employee Program

LYNPARZA
(olaparib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Lynparza (olaparib) is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1, PARP2, and PARP3. PARP enzymes are involved in normal cellular functions, such as DNA transcription and DNA repair. Lynparza inhibits growth of select tumor cell lines and decreases tumor growth (1).

Regulatory Status

FDA-approved indications: Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated: (1)

1. Ovarian cancer
    a. For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCA*m or s*BRCA*m) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy
    b. 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:
        i. a deleterious or suspected deleterious *BRCA* mutation, and/or
        ii. genomic instability
    c. For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic *BRCA*-mutated recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy
2. Breast cancer
    a. For the adjuvant treatment of adult patients with deleterious or suspected deleterious g*BRCA*m human epidermal growth factor receptor 2 (HER2)-negative high risk early breast cancer who have been treated with neoadjuvant or adjuvant chemotherapy
    b. For the treatment of breast cancer in in patients with deleterious or suspected deleterious g*BRCA*m, human epidermal growth factor receptor 2 (HER2)-negative

metastatic breast cancer who have previously 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 treatment

3. Pancreatic cancer
    a. For the maintenance treatment of adult patients with deleterious or suspected deleterious g*BRCA*m metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen
4. Prostate cancer
    a. 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 enzalutamide or abiraterone
    b. In combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious *BRCA*-mutated (*BRCA*m) metastatic castration-resistant prostate cancer (mCRPC).

Lynparza is associated with the development of myelodysplastic syndrome, acute myeloid leukemia, pneumonitis, and venous thromboembolism (1).

The safety and effectiveness of Lynparza in patients less than 18 years of age have not been established (1).

Summary

Lynparza (olaparib) is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1, PARP2, and PARP3. PARP enzymes are involved in normal cellular functions, such as DNA transcription and DNA repair. Lynparza inhibits growth of select tumor cell lines and decreases tumor growth. The safety and effectiveness of Lynparza in patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate, and cost-effective use of Lynparza while maintaining optimal therapeutic outcomes.

References

1. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2023.
2. NCCN Drugs & Biologics Compendium® Olaparib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2024.