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Section:	Prescription Drugs	**Effective Date:**	April 1, 2024
Subsection:	Antineoplastic Agents	**Original Policy Date:**	January 16, 2015
Subject:	Lynparza	**Page:**	1 of 7

Last Review Date: March 8, 2024

Lynparza

Description

Lynparza (olaparib)

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).

Related policies
Akeega, Rubraca, Talzenna, Zejula

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Lynparza may be considered **medically necessary** if the conditions indicated below are met.

Lynparza may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer
    a. Patient has had a complete or partial response to platinum-based chemotherapy
    b. *BRCA*-positive mutation

2. Advanced epithelial ovarian, fallopian tube or primary peritoneal cancer
    a. Patient has had a complete or partial response to platinum-based chemotherapy and **ONE** of the following:
        1. *BRCA*-positive mutation
        2. Used in combination with bevacizumab
            a. Cancer is associated with homologous recombination deficiency (HRD) positive status defined by at least **ONE** of the following:
                i. Deleterious or suspected deleterious *BRCA* mutation
                ii. Genomic instability

3. Early breast cancer
    a. High risk
    b. *BRCA*-positive mutation
    c. HER2-negative
    d. Previously treated with neoadjuvant or adjuvant chemotherapy

4. Metastatic breast cancer
    a. *BRCA*-positive mutation
    b. HER2-negative
    c. Prior therapy with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting
    d. If HR-positive must have **ONE** of the following:
        i. Previously been treated with prior endocrine therapy
        ii. Considered an inappropriate candidate for endocrine therapy

5. Metastatic pancreatic cancer
    a. *BRCA*-positive mutation
    b. Disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

6. Metastatic castration-resistant prostate cancer (mCRPC) and **ONE** of the following:
    a. Homologous recombination repair (HRR) gene mutation
        i. Disease progressed following prior treatment with enzalutamide or abiraterone
        ii. Patient has had a bilateral orchiectomy **OR** patient will be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently
    b. *BRCA*-positive mutation
        i. Used in combination with abiraterone
        ii. Used in combination with prednisone or prednisolone
        iii. Patient has had a bilateral orchiectomy **OR** patient will be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Recurrent or advanced epithelial ovarian, fallopian tube or primary peritoneal cancer

2. Metastatic breast cancer
3. Metastatic pancreatic cancer
4. Metastatic castration-resistant prostate cancer (mCRPC)

AND the following for all indications:

a. **NO** disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity
100 mg	360 tablets per 90 days
150 mg	

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above*

***NO** renewal for early breast cancer

Rationale

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 January 18, 2024.

Policy History

Date	Action
January 2015	Addition to PA
March 2015	Annual review and reference update
June 2016	Annual editorial review and reference update Policy change from 5.04.52 to 5.21.52
June 2017	Annual editorial review and reference update Addition of unacceptable toxicity to renewal section
September 2017	Annual review Addition of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer Addition of quantity limits Removal of no concurrent therapy with other agents for the treatment of ovarian cancer
February 2018	Addition of metastatic breast cancer to initiation and renewal criteria. Addition of *BRCA* positive, prior therapy with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting, and If HR-positive, must have previously been treated with prior endocrine therapy, or be considered an inappropriate candidate for endocrine therapy to initiation criteria for the diagnosis of metastatic breast cancer Change in quantity for the 50mg capsules from 672 to 1456
March 2018	Annual review
January 2019	Addition of new indication: *BRCA*-mutated advanced epithelial ovarian, fallopian tube or primary peritoneal cancer. Removal of Lynparza 50mg capsules
March 2019	Annual review
May 2019	Changed quantity limit to 360 tablets per 90 days for both strengths of Lynparza
June 2019	Annual review
January 2020	Addition of indication: metastatic pancreatic cancer
March 2020	Annual review
May 2020	Addition of indication: used 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 deleterious or suspected deleterious *BRCA* mutation, and/or genomic instability. Addition of indication: 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
September 2020	Annual review
June 2021	Annual review and reference update
February 2022	Changed initiation duration from 6 to 12 months per FEP
April 2022	Addition of indication per PI update: early breast cancer
June 2022	Annual review and reference update
September 2022	Per PI update, removed indication for advanced ovarian cancer after three or more prior lines of chemotherapy
December 2022	Annual review and reference update
March 2023	Annual review and reference update
June 2023	Per PI update, added indication of *BRCA* mutation for mCRPC
September 2023	Annual review and reference update
December 2023	Annual editorial review and reference update. Per PI update, added BRCA-positive mutation requirement to recurrent ovarian cancer
March 2024	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 8, 2024 and is effective on April 1, 2024.