

5.21.052

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**Last Review Date:** June 11, 2026

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## Lynparza

### Description

#### Lynparza (olaparib)

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#### 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 (*gBRCAm* or *sBRCAm*) 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

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- 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 *gBRCA*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 *gBRCA*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 *gBRCA*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 (*BRCAm*) 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).

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**Related policies**

Akeega, Rubraca, Talzena, Zejula

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## 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

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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

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## 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

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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

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#### 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.

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## References

1. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; July 2025.
2. NCCN Drugs & Biologics Compendium® Olaparib 2026. National Comprehensive Cancer Network, Inc. Accessed on April 27, 2026.

## Policy History

| Date           | Action                                                                                                                                                                                                                                                                                                                                                                                                                                                                                     |
|----------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| January 2015   | Addition to PA                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| March 2015     | Annual review and reference update                                                                                                                                                                                                                                                                                                                                                                                                                                                         |
| June 2016      | Annual editorial review and reference update<br>Policy change from 5.04.52 to 5.21.52                                                                                                                                                                                                                                                                                                                                                                                                      |
| June 2017      | Annual editorial review and reference update<br>Addition of unacceptable toxicity to renewal section                                                                                                                                                                                                                                                                                                                                                                                       |
| September 2017 | Annual review<br>Addition of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer<br>Addition of quantity limits<br>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.<br>Addition of <i>BRCA</i> 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<br>Change in quantity for the 50mg capsules from 672 to 1456 |
| March 2018     | Annual review                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| January 2019   | Addition of new indication: <i>BRCA</i> -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                                                                                                                        |

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|                | status defined by either: a deleterious or suspected deleterious <i>BRCA</i> 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 <i>BRCA</i> mutation for mCRPC                                                                                                                                                                                                                                           |
| September 2023 | Annual review and reference update                                                                                                                                                                                                                                                                          |
| December 2023  | Annual editorial review and reference update. Per PI update, added <i>BRCA</i> -positive mutation requirement to recurrent ovarian cancer                                                                                                                                                                   |
| March 2024     | Annual review and reference update                                                                                                                                                                                                                                                                          |
| December 2024  | Annual review and reference update                                                                                                                                                                                                                                                                          |
| June 2025      | Annual review and reference update                                                                                                                                                                                                                                                                          |
| June 2026      | Annual review and reference update                                                                                                                                                                                                                                                                          |

### Keywords

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**This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 11, 2026 and is effective on July 1, 2026.**