

5.21.52

Section:	Prescription Drugs	Effective Date:	April 1, 2020
Subsection:	Antineoplastic Agents	Original Policy Date:	January 16, 2015
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Last Review Date: March 13, 2020

Lynparza

Description

Lynparza (olaparib)

Background

Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. Lynparza is intended for women with heavily pretreated ovarian cancer that is associated with defective BRCA genes, or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. Ovarian cancer forms in the ovary, one of a pair of female reproductive glands where ova, or eggs, are formed. The BRCA genes are involved with repairing damaged DNA and normally work to suppress tumor growth. Women with mutations resulting in defective BRCA genes are more likely to get ovarian cancer. Additionally, Lynparza has gained FDA approval for the treatment of adults with metastatic breast cancer who have, or are suspected to have, deleterious germline BRCA-mutated (gBRCAm) breast cancer. It is approved for women with breast cancer after receiving chemotherapy treatment in the neoadjuvant (used to shrink the cancer before surgery), adjuvant (systemic chemotherapy), or metastatic setting. Lynparza is also approved for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen (1).

Regulatory Status

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

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1. For the maintenance treatment of adult patients with deleterious or suspected deleterious germline or somatic BRCA-mutated (gBRCAm or sBRACAm) advanced epithelial ovarian, fallopian tube or primary peritoneal cancer who are in complete or partial response to first-line platinum-based chemotherapy
2. For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in a complete or partial response to platinum-based chemotherapy
3. For the treatment of adult patients with deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer who has been treated with three or more prior lines of chemotherapy
4. For the treatment of breast cancer in in patients with deleterious or suspected deleterious gBRCAm, 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
5. For the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

Lynparza is associated with the development of myelodysplastic syndrome, a condition where the bone marrow is unable to produce enough functioning blood cells; acute myeloid leukemia, a bone marrow cancer; and lung inflammation (1).

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

Related policies

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** for use in patients 18 years of age and older with advanced ovarian cancer with BRCA-positive mutation or recurrent or advanced epithelial ovarian, fallopian tube or primary peritoneal cancer; or in patients with deleterious or suspected deleterious BRCA mutation, HER2-negative metastatic breast cancer; or in patients

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with deleterious or suspected deleterious BRCA mutation metastatic pancreatic cancer and if the conditions indicated below are met.

Lynparza may be considered **investigational** in patients less than 18 years of age and for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

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

1. Advanced ovarian cancer
 - a. BRCA-positive mutation
 - b. Prior therapy with 3 or more lines of chemotherapy
2. Recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer
 - a. Patient has had a complete or partial response to platinum-based chemotherapy
3. Advanced epithelial ovarian, fallopian tube or primary peritoneal cancer
 - a. BRCA-positive mutation
 - b. Patient has had a complete or partial response to platinum-based 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

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- b. Disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

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

1. Advanced ovarian cancer
2. Recurrent or advanced epithelial ovarian, fallopian tube or primary peritoneal cancer
3. Metastatic breast cancer
4. Metastatic pancreatic cancer

AND the following:

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

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity

Strength	Quantity per Day Supply
100 mg	360 tablets per 90 days
150 mg	

Duration 6 months

Prior – Approval *Renewal* Limits

Quantity

Strength	Quantity per Day Supply
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100 mg	360 tablets per 90 days
150 mg	

Duration 12 months

Rationale

Summary

Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. Lynparza is intended for women with heavily pretreated ovarian cancer that is associated with defective BRCA genes, or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. Lynparza is indicated as monotherapy in patients with deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer that have been treated with three or more prior lines of chemotherapy. Additionally, Lynparza has gained FDA approval for the treatment of adults with metastatic breast cancer who have, or are suspected to have, deleterious germline BRCA-mutated breast cancer. Lynparza is also approved for the maintenance treatment of adult patients with deleterious or suspected deleterious gBRCAm metastatic pancreatic adenocarcinoma whose disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen. 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; December 2019.

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

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	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 qty 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

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 13, 2020 and is effective on April 1, 2020.