UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1149-12
Program	Prior Authorization/Notification
Medication	Lynparza® (olaparib)
P&T Approval Date	2/2015, 2/2016, 12/2016, 11/2017, 3/2018, 3/2019, 2/2020, 7/2020, 7/2021, 5/2022, 10/2022, 7/2023
Effective Date	10/1/2023; Oxford only: 10/1/2023

1. **Background:**

Lynparza (olaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated 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. Lynparza is also indicated for the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, who are in complete or partial response to platinum-based chemotherapy. Lynparza is also indicated 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 or genomic instability.

Lynparza is also indicated in patients with deleterious or suspected deleterious g*BRCA*m, human epidermal growth factor receptor 2 (HER2)-negative high risk early, recurrent, or metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant or, in the setting of metastatic breast cancer, the 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. The National Comprehensive Cancer Network (NCCN) also recommends Lynparza therapy in patients with deleterious or suspected deleterious gBRCAm human epidermal growth factor receptor 2 (HER2)-positive recurrent unresectable or metastatic breast cancer. Patients with high risk early breast cancer should continue treatment for a total of 1 year, or until disease recurrence, or unacceptable toxicity, whichever occurs first.

Lynparza isindicated 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. Lynparza is also indicated in combination with abiraterone and prednisone or prednisolone for the treatment of adult patients with deleterious or suspected deleterious BRCA-mutated (BRCAm) mCRPC. Patients receiving Lynparza for mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy.

Lynparza is indicated 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.

The NCCN also recommends Lynparza therapy in patients with uterine sarcoma as single-agent second-line therapy.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. **Coverage Criteria[a]:**

A. <u>Patients less than 19 years of age</u>

1. **Lynparza** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. Breast Cancer (High Risk Early Breast Cancer)

1. **Authorization**

   a. **Lynparza** will be approved based on **<u>all</u>** of the following:

      (1) Diagnosis of high risk early breast cancer

      -AND-

      (2) Presence of deleterious or suspected deleterious germline BRCA-mutations (gBRCAm)

      -AND-

      (3) Disease is human growth factor receptor 2 (HER2)-negative

      -AND-

      (4) **One** of the following:

         i. Patient is hormone receptor (HR) negative

         -OR-

         ii. **Both** of the following:

            1. Patient is hormone receptor (HR) positive

2. Patient is continuing concurrent treatment with endocrine therapy

-AND-

(5) Patient has been treated with neoadjuvant or adjuvant chemotherapy

-AND-

(6) Treatment duration has not exceeded 12 months of therapy

Authorization will be issued for 12 months.

C. Breast Cancer (Metastatic or Recurrent Breast Cancer)

1. **Initial Authorization**

a. **Lynparza** will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Metastatic breast cancer
(b) Recurrent breast cancer

-AND-

(2) Presence of deleterious or suspected deleterious germline BRCA-mutations (g*BRCA*m)

-AND-

(3) **One** of the following:

(a) **Both** of the following:

1. Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

2. **One** of the following:

i. Disease is hormone receptor (HR) negative

-OR-

ii. **Both** of the following:

a. Disease is hormone receptor (HR) positive

-AND-

b. **One** of the following:
- Disease has progressed on previous endocrine therapy
- Provider attestation that treatment with endocrine therapy is inappropriate

-OR-

(b) Disease is human epidermal growth factor receptor 2 (HER2)-positive

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lynparza** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lynparza therapy

Authorization will be issued for 12 months.

D. Ovarian Cancer (Maintenance Therapy)

1. **Initial Authorization**

a. **Lynparza** will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Epithelial ovarian cancer
(b) Fallopian tube cancer
(c) Primary peritoneal cancer

-AND-

(2) Disease is advanced or recurrent

-AND-

(3) **One** of the following:

(a) Patient has had a complete or partial response to platinum-based chemotherapy

-OR-

(b) **Both** of the following:

i. Patient has had a complete or partial response to first-line platinum-based chemotherapy

-AND-

ii. **One** of the following:

1. Presence of deleterious or suspected deleterious germline or somatic *BRCA*-mutations

-OR-

2. **Both** of the following:

a. Cancer is associated with homologous recombination deficiency (HRD)-positive status defined by either a deleterious or suspected deleterious BRCA mutation or genomic instability

-AND-

b. Used in combination with bevacizumab (e.g., Avastin, Mvasi)

-AND-

(4) Request is for maintenance therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lynparza** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lynparza therapy

Authorization will be issued for 12 months.

E. Ovarian Cancer (Treatment)

1. **Initial Authorization**

a. **Lynparza** will be approved based on **all** of the following criteria:

(1) Diagnosis of **one** of the following:

(a) Epithelial ovarian cancer
(b) Fallopian tube cancer
(c) Primary peritoneal cancer

(2) Disease is one of the following:

(a) Advanced
(b) Persistent

(c) Recurrent

-AND-

(3) Presence of deleterious or suspected deleterious germline *BRCA*-mutation

-AND-

(4) Patient has been treated with two or more prior lines of chemotherapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lynparza** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lynparza therapy

Authorization will be issued for 12 months.

F. Pancreatic Cancer

1. **Initial Authorization**

a. **Lynparza** will be approved based on **all** of the following criteria:

(1) Diagnosis of pancreatic adenocarcinoma

-AND-

(2) Disease is metastatic

-AND-

(3) Presence of deleterious or suspected deleterious germline *BRCA1/2*-mutation

-AND-

(4) Disease has **not** progressed while receiving at least 16 weeks of a first-line platinum-based chemotherapy regimen.

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lynparza** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lynparza therapy

Authorization will be issued for 12 months.

G. Prostate Cancer

1. **Initial Authorization**

a. **Lynparza** will be approved based on **all** of the following criteria:

(1) Diagnosis of metastatic castration-resistant prostate cancer

-AND-

(2) **One** of the following:

(a) **Both** of the following:

i. Presence of deleterious or suspected deleterious germline or somatic homologous recombination repair (HRR) gene mutations

-AND-

ii. Disease has progressed following prior treatment with **one** of the following:

1. Enzalutamide (Xtandi)
2. Abiraterone (e.g., Zytiga, Yonsa)

-OR-

(b) **All** of the following:

i. Presence of deleterious or suspected deleterious *BRCA*-mutation

-AND-

ii. Used in combination with abiraterone (e.g., Zytiga, Yonsa)

-AND-

iii. Used in combination with one of the following:

1. Prednisone
2. Prednisolone

-AND-

(3) **One** of the following:

(a) Used in combination with a gonadotropin-releasing hormone (GnRH)

analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

-OR-

(b) Patient has had bilateral orchiectomy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lynparza** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lynparza therapy

Authorization will be issued for 12 months.

H. Uterine Neoplasms

1. **Initial Authorization**

a. **Lynparza** will be approved based on **both** of the following criteria:

(1) Diagnosis of uterine sarcoma

-AND-

(2) **Not** used as first-line therapy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Lynparza** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Lynparza therapy

Authorization will be issued for 12 months.

I. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific

benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. **Additional Clinical Rules:**

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, Inc, May 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed June 13, 2023.

Program	Prior Authorization/Notification – Lynparza (olaparib)
Change Control	
2/2015	New program for Lynparza approved by FDA on 12/19/14.
2/2016	Annual review. Revised formatting of criteria. Changed initial and reauthorization period to 12 months.
10/2016	Annual review. Updated references.
11/2017	Annual review. Updated criteria. Updated references.
3/2018	Added breast cancer to coverage criteria.
3/2019	Annual review. Updated criteria to reflect NCCN recommendations and updated prescribing information. Updated background and references.
2/2020	Annual review. Added pancreatic cancer and NCCN recommended regimen criteria. Updated background and references.
7/2020	Added criteria for metastatic castration resistant prostate cancer due to expanded indication. Separated ovarian cancer criteria into maintenance therapy and treatment. Updated background and references.
7/2021	Updated criteria for breast cancer to reflect NCCN recommendations. Updated formatting for ovarian cancer without change in clinical intent. Updated background and references.
5/2022	Added criteria for high risk early breast cancer per label. Clarified metastatic and recurrent breast cancer in separate criteria. Added criteria for uterine neoplasms per NCCN recommendations. Updated background and references.
10/2022	Updated background to reflect per prescribing information a voluntary indication withdrawal for patients with ovarian cancer who have been treated with three or more prior lines of chemotherapy.
7/2023	Added criteria for BRCA-mutated metastatic castration resistant

	prostate cancer per label. Updated background and references.