UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Lynparza

Program	Prior Authorization
Medication	Lynparza™ (olaparib)
Markets in Scope	Arizona, California, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania-CHIP, Rhode Island, South Carolina
Issue Date	9/2015
Pharmacy and Therapeutics Approval Date	7/2020
Effective Date	9/2020

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, or for the treatment of adult patients with deleterious or suspected deleterious g*BRCA*m advanced ovarian cancer who have been treated with three or more prior lines of 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.[1]

Lynparza is also indicated in patients with deleterious or suspected deleterious g*BRCA*m, human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer who have 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.[1]

Lynparza is also indicated 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. Patients receiving Lynparza for mCRPC should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had a bilateral orchiectomy.

Finally, Lynparza is indicated 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.

2. Coverage Criteria:

A. 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:

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

-AND-

- **One** of the following:
  - Presence of deleterious or suspected deleterious germline or somatic *BRCA*-mutations

-OR-

- **Both** of the following:

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

B. Ovarian Cancer (Treatment)

1. Initial Authorization

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

(1) Diagnosis of advanced, persistent, or recurrent ovarian cancer

-AND-

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

-AND-

(3) 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.

C. Breast Cancer

1. Initial Authorization

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

(1) Diagnosis of breast cancer

-AND-

(2) Disease is **one** of the following:

(a) Metastatic
(b) Recurrent

-AND-

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

-AND-

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

-AND-

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

(a) Disease is hormone receptor (HR) negative

-OR-

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

i. Disease is hormone receptor (HR) positive

-AND-

ii. **One** of the following:

- Disease has progressed on previous endocrine therapy
- Provider attestation that treatment with endocrine therapy is inappropriate for the patient's disease

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. 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.

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

-AND-

(3) Disease has progressed following prior treatment with **one** of the following:

(a) Enzalutamide (Xtandi)
(b) Abiraterone (e.g., Zytiga, Yonsa)

-AND-

(4) **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.

F. NCCN Recommended Regimens

1. Initial Authorization

a. **Lynparza** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Lynparza therapy

Authorization will be issued for 12 months.

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., May2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed June 3, 2020.

Program	Prior Authorization – Lynparza (olaparib)
Change Control	
9/2015	New policy
10/2016	• Added disease is 'Persistent, Recurrent' in addition to existing 'Advanced' • Removed prescriber requirement • Updated policy template.

12/2016	Annual review. Updated references.
11/2017	Updated criteria due to expanded indication. Updated background and references.
3/2018	Added breast cancer to coverage criteria. Updated background and references. Added NCCN recommended regimen review criteria.
3/2019	Updated background and criteria to reflect expanded indication. Updated references.
2/2020	Added pancreatic cancer review criteria due to expanded label. 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. Removed requirement of FDA test to document BRCA mutations. Removed requirement of prior chemotherapy for breast cancer indication. Updated background and references.