UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Lynparza

Program	Prior Authorization
Medication	Lynparza™ (olaparib)
Issue Date	9/2015
Pharmacy and Therapeutics Approval Date	3/2018
Effective Date	5/2018

1. Background:

Lynparza (olaparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated 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. Lynparza is also indicated for monotherapy in patients with deleterious or suspected deleterious germline BRCA mutated (*gBRCAm*, as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.[1]

Lynparza is also indicated 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.[1]

2. Coverage Criteria:

A. Ovarian Cancer

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) **One** of the following:

(a) Both of the following:

i. Disease is recurrent
ii. Patient has had a complete or partial response to platinum-based chemotherapy

-OR-

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

i. Disease is **one** of the following:

(a) Advanced
(b) Persistent
(c) Recurrent

-AND-

ii. Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by an FDA-approved test

-AND-

iii. History of failure, contraindication, or intolerance to three or more prior lines of chemotherapy (e.g., paclitaxel with cisplatin)

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. 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 as detected by an FDA-approved test

-AND-

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

-AND-

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

(a) **Both** of the following:
i. Disease is hormone receptor (HR) negative
ii. Patient has been previously treated with chemotherapy (e.g., anthracycline, taxane)

-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 patients disease

Authorization will be issued for 12 months.

2. <u>Reauthorization</u>

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. 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. References:

1. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP, Inc, January 2018.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed January 24, 2018.

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.