

## Lynparza (olaparib) (Oral)

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### I. Length of Authorization

Coverage will be provided for six months and may be renewed.

- First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer: may be renewed up to 2 years of treatment

### II. Dosing Limits

#### A. Quantity Limit (max daily dose) [Pharmacy Benefit]:

- Lynparza 100 mg oral tablet: 2 tablets daily
- Lynparza 150 mg oral tablet: 4 tablets daily

#### B. Max Units (per dose and over time) [Medical Benefit]:

- 600 mg daily

### III. Initial Approval Criteria

Coverage for drug is provided in the following conditions:

- Patient must be 18 years of age or older; **AND**
- Must be used as a single agent; **AND**

#### Ovarian Cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer) †

- Patient is in complete or partial response to platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
  - Patient will start treatment no later than 8 weeks after their most recent platinum-containing regimen; **AND**
    - Used for maintenance treatment of recurrent disease after at least two prior platinum-containing regimens; **OR**
    - Patient has deleterious or suspected deleterious germline or somatic *BRCA*-mutated (g*BRCA*m or s*BRCA*m) disease as detected by an FDA-approved test\*; **AND**

- Used as maintenance treatment of advanced disease after first-line platinum based therapy; **OR**
- Patient must have deleterious or suspected deleterious germline *BRCA*-mutated (g*BRCA*m) disease as detected by an FDA-approved test\*; **AND**
  - Patient must have advanced, persistent or recurrent disease; **AND**
  - Patient has received at least three prior lines of chemotherapy

#### **Breast Cancer †**

- Patient has deleterious or suspected deleterious germline *BRCA*-mutated disease as detected by an FDA-approved test\*; **AND**
- Patient has HER2-negative recurrent or metastatic disease; **AND**
- Patient has received prior chemotherapy; **AND**
  - Patient has hormone receptor (HR)-negative disease; **OR**
  - Patient has hormone receptor (HR)-positive disease that is refractory to endocrine therapy or endocrine therapy is considered inappropriate; **OR**
  - Patient has symptomatic visceral disease or visceral crisis.

\*<http://www.fda.gov/CompanionDiagnostics>

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s)

## **IV. Renewal Criteria**

Authorizations can be renewed based on the following criteria:

- Patient continues to meet the criteria identified in section III; **AND**
- Tumor response with stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include the following: pneumonitis, development of myelodysplastic syndrome/acute myeloid leukemia (MDS/AML); etc.; **AND**

#### **Ovarian Cancer (First-Line Maintenance Treatment of *BRCA*-mutated Disease)\***

- Patient has NOT received more than 2 years of treatment; **OR**
  - Patient experienced a complete response (i.e., no radiological evidence of disease) at 2 years
- \*(Requests for extended treatment beyond two years will be treated on a case-by-case basis)*

## **V. Dosage/Administration**

<b>Indication</b>	<b>Dose</b>
Ovarian Cancer and Breast Cancer	Administer 300 mg (two 150 mg tablets) orally, twice daily. – First-Line Maintenance Treatment of <i>BRCA</i> -mutated Advanced Ovarian Cancer

	<ul style="list-style-type: none"> <li>• Continue treatment until disease progression, unacceptable toxicity, or completion of 2 years of treatment. Patients with a complete response (no radiological evidence of disease) at 2 years should stop treatment. Patients with evidence of disease at 2 years, who in the opinion of the treating healthcare provider can derive further benefit from continuous treatment, can be treated beyond 2 years.</li> </ul> <p>– All Other Indications</p> <ul style="list-style-type: none"> <li>• Continue treatment until disease progression or unacceptable toxicity.</li> </ul>
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## VI. Billing Code/Availability Information

### HCPCS code:

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals (*Hospital Outpatient Use ONLY*)

### NDC:

- Lynparza 100 mg oral tablet: 00310-0668-xx
- Lynparza 150 mg oral tablet: 00310-0679-xx

## VII. References

1. Lynparza capsules [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; December 2018. Accessed December 2018.
2. Lynparza tablets [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; January 2018. Accessed January 2018.
3. Pujade-Lauraine E, Ledermann JA, Selle F, et al. Olaparib tablets as maintenance therapy in patients with platinum-sensitive, relapsed ovarian cancer and a BRCA1/2 mutation (SOLO2/ENGOT-Ov21): a double-blind, randomised, placebo-controlled, phase 3 trial. *Lancet Oncol.* 2017 Jul 25. pii: S1470-2045(17)30469-2.
4. Ledermann JA, Harter P, Gourley C, et al. Overall survival in patients with platinum-sensitive recurrent serous ovarian cancer receiving olaparib maintenance monotherapy: an updated analysis from a randomised, placebo-controlled, double-blind, phase 2 trial. *Lancet Oncol.* 2016 Nov;17(11):1579-1589.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) olaparib. National Comprehensive Cancer Network, 2018. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc.” To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed December 2018.
6. Robson MR, Im S, Senjus E, et al. Olaparib for metastatic breast cancer in patients with germline BRCA mutation. *NEJM.* 2017 Aug 10 (377): 523-533.

## Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of right male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast

### LYNPARZA (olaparib) Prior Auth Criteria

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ICD-10	ICD-10 Description
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C56.1	Malignant neoplasm of ovary, right ovary
C56.2	Malignant neoplasm of ovary, left ovary
C56.9	Malignant neoplasm of ovary, unspecified
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament

ICD-10	ICD-10 Description
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary

## Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determination (NCD) and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <http://www.cms.gov/medicare-coverage-database/search/advanced-search.aspx>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	Applicable State/US Territory	Contractor
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC