Lynparza (olaparib)
(Oral)

Document Number: IC-0227

Last Review Date: 04/06/2021
Date of Origin: 1/06/2015
Dates Reviewed: 01/2015, 10/2015, 10/2016, 09/2017, 02/2018, 01/2019, 01/2020, 06/2020, 04/2021

I. Length of Authorization[1]

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

First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer: may be renewed for up to 2 years of treatment **(Requests for extended treatment beyond two years will be treated on a case-by-case basis. See Section V.)*

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

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

B. Max Units (per dose and over time) [HCPCS Unit]:

- 600 mg daily

III. Initial Approval Criteria[1]

Coverage for drug is provided in the following conditions:

- Patient must be 18 years of age or older; **AND**

Universal Criteria

- Patient has not received prior treatment with a PARP-inhibitor (i.e., olaparib, rucaparib, or talazoparib) prior to initiating therapy; **AND**
- Patient will avoid concomitant therapy with any of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole, etc.), if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **OR**
  - Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, etc.); **AND**

Ovarian Cancer (epithelial ovarian, fallopian tube, or primary peritoneal cancer) † Φ [1,2,4,6-8,10,11]

- Used as maintenance treatment; **AND**
  - Patient has stage II-IV carcinosarcoma or clear cell carcinoma; **AND**
    - Patient has deleterious or suspected-deleterious BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test❖; **AND**
    - Patient is in complete or partial response after primary therapy; **AND**
      - Used as a single agent; **OR**
      - Used in combination with bevacizumab if used as part of primary therapy for HR deficient disease**; **OR**
  - Patient has stage III-IV high-grade serous or grade 2/3 endometrioid carcinoma; **AND**
    - Patient is in complete or partial response after primary therapy; **AND**
      - Used as a single agent; **AND**
        - Patient has deleterious or suspected-deleterious BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test❖; **OR**
      - Used in combination with bevacizumab if used as part of primary therapy for HR deficient disease**; **OR**
  - Patient has recurrent disease; **AND**
    - Patient has deleterious or suspected-deleterious BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test❖; **AND**
    - Used as a single agent; **AND**
    - Patient is in complete or partial response after most recent platinum-based chemotherapy (i.e., platinum-sensitive); **AND**
    - Patient has completed two or more lines of previous platinum-based therapy; **OR**
- Used as subsequent therapy; **AND**
  - Patient has advanced, persistent, or recurrent disease; **AND**
  - Patient has deleterious or suspected-deleterious germline BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test❖; **AND**
  - Used as single-agent; **AND**
  - Used after at least two prior chemotherapy regimens

*** Note: HR-deficient disease defined as a deleterious or suspected-deleterious BRCA-mutation with or without genomic instability*

Breast Cancer † [1,4,5]

- Patient has deleterious or suspected-deleterious germline BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent for recurrent or metastatic disease; **AND**
  - Patient has HER2-negative disease; **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 hormone receptor (HR)-positive disease with visceral crisis; **OR**

  - Patient has HER2-positive disease ‡; **AND**
    - Patient has hormone receptor (HR)-negative disease; **OR**
    - Patient has hormone receptor (HR)-positive disease with or without endocrine therapy

Pancreatic Adenocarcinoma † Φ [1,4,9]

- Patient has deleterious or suspected-deleterious germline BRCA-mutated disease as detected by any FDA-approved or CLIA-compliant test❖; **AND**
- Used as a single agent for maintenance treatment of metastatic disease; **AND**
- Disease has not progressed on at least 16 weeks of a first-line platinum-based chemotherapy regimen

Prostate Cancer † [1,12]

- Patient has deleterious or suspected-deleterious germline or somatic homologous repair (HRR) gene-mutated disease detected by any FDA-approved or CLIA-compliant test❖; **AND**
- Patient does not have a PPP2R2A mutation; **AND**
- Used as a single agent for metastatic castration-resistant disease; **AND**
- Patient has progressed on prior treatment with androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, etc.); **AND**
  - Patient has been treated with taxane-based chemotherapy; **OR**
  - Patient is not fit for taxane-based chemotherapy; **AND**
    - Patient received prior novel hormone therapy; **AND**
    - Patient had no prior docetaxel OR patient received prior docetaxel and has no visceral metastases present; **AND**
- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria[1,2,4-9,11]

Authorizations can be renewed based on the following criteria:

- Patient continues to meet universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**

- Disease response with treatment as defined by 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: pneumonitis, development of myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), venous thromboembolic events (including pulmonary embolism), etc.; **AND**

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

- Patient has NOT received more than 2 years of treatment

**(Requests for extended treatment beyond two years will be treated on a case-by-case basis. See Section V.)*

V. Dosage/Administration[1]

Indication	Dose
Ovarian Cancer, Breast Cancer, Pancreatic Adenocarcinoma, & Prostate Cancer	Administer 300 mg (two 150 mg tablets) orally, twice daily. – First-Line Maintenance Treatment of BRCA-mutated Advanced Ovarian Cancer as a Single Agent or in Combination with Bevacizumab • 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. – All Other Indications • Continue treatment until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS code:

- J8999 – Prescription drug, oral, chemotherapeutic, nos

NDC:

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

VII. References

1. Lynparza tablets [package insert]. Wilmington, DE; AstraZeneca Pharmaceuticals LP; December 2020. Accessed March 2021.
2. 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.

3. 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.
4. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) olaparib. National Comprehensive Cancer Network, 2021. 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 March 2021.
5. Robson MR, Im S, Senkus E, et al. Olaparib for metastatic breast cancer in patients with germline BRCA mutation. NEJM. 2017 Aug 10 (377): 523-533.
6. Ledermann J, Harter P, Gourley C, et al. Olaparib maintenance therapy in platinum-sensitive relapsed ovarian cancer. N Engl J Med. 2012 Apr 12;366(15):1382-92. Doi: 10.1056/NEJMoa1105535. Epub 2012 Mar 27.
7. Moore K, Colombo N, Scambia G, et al. Maintenance Olaparib in Patients with Newly Diagnosed Advanced Ovarian Cancer. N Engl J Med. 2018 Dec 27;379(26):2495-2505. Doi: 10.1056/NEJMoa1810858. Epub 2018 Oct 21.
8. Domchek SM, Aghajanian C, Shapira-Frommer R, et al. Efficacy and safety of olaparib monotherapy in germline BRCA1/2 mutation carriers with advanced ovarian cancer and three or more lines of prior therapy. Gynecol Oncol. 2016 Feb;140(2):199-203. Doi: 10.1016/j.ygyno.2015.12.020. Epub 2015 Dec 23.
9. Golan T, Hammel P, Reni M, et al. Maintenance Olaparib for Germline *BRCA*-Mutated Metastatic Pancreatic Cancer. N Engl J Med. 2019 Jul 25;381(4):317-327. Doi: 10.1056/NEJMoa1903387. Epub 2019 Jun 2.
10. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Ovarian Cancer Including Fallopian Tube Cancer and Primary Peritoneal Cancer. Version 1.2021. National Comprehensive Cancer Network, 2021. 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 March 2021.
11. Ray-Coquard I, Pautier P, Pignata S, et al. Olaparib Plus Bevacizumab as First-Line Maintenance in Ovarian Cancer. N Engl J Med. 2019 Dec 19;381(25):2416-2428. doi: 10.1056/NEJMoa1911361.
12. de Bono J, Mateo J, Fizazi K, et al. Olaparib for Metastatic Castration-Resistant Prostate Cancer. N Engl J Med. 2020 Apr 28. doi: 10.1056/NEJMoa1911440.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C24.1	Malignant neoplasm of ampulla of Vater
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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
C61	Malignant neoplasm of prostate

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), Local Coverage Determinations (LCDs), and Local Coverage Articles (LCAs) 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/LCA): 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

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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