Lynparza® (olaparib)
(Oral)

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I. Length of Authorization [1]

Coverage will be provided for 6 months and may be renewed.

- First-Line Maintenance Treatment of BRCA1/2 mutated Advanced Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer: may be renewed for up to 2 years of treatment *(Note: Requests for extended treatment beyond two years will be treated on a case-by-case basis. See Section V.)*
- Adjuvant Treatment of Breast Cancer: may be renewed for up to 1 year of treatment

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]:

- All indications: 600 mg daily

III. Initial Approval Criteria [1]

Coverage for drug is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,4]

- Patient has not received prior treatment with a PARP-inhibitor (i.e., niraparib, rucaparib, talazoparib, etc.) prior to initiating therapy unless otherwise specified; **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with strong or moderate CYP3A inhibitors (e.g., fluconazole, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications; **AND**

- Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, carbamazepine, St. John's Wort, bosentan, etc.); **AND**

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer † ‡ Φ [1,2,4,6-8,10,11]

- Used as first-line maintenance treatment for advanced Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer; **AND**
  - Patient is in complete or partial response to first-line platinum-based therapy; **AND**
    - Patient has germline or somatic BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test❖; **AND**
      - Used as a single agent; **OR**
    - Patient has homologous recombination deficiency (HRD)* as detected by an FDA-approved or CLIA-compliant test❖; **AND**
      - Used in combination with bevacizumab; **OR**
- Used as maintenance treatment for recurrent Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, Grade 1 Endometrioid Carcinoma, Mucinous Carcinoma of the Ovary, or Low-Grade Serous Carcinoma; **AND**
  - Patient is in complete or partial response after at least two prior lines of platinum-based therapy (i.e., platinum sensitive); **AND**
  - Used as a single agent; **AND**
  - Patient has germline or somatic BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test❖; **AND**
  - Patient has not progressed on prior PARP-inhibitor therapy, if previously received; **OR**
- Used as maintenance treatment for stage II-IV High-Grade Serous or Grade 2/3 Endometrioid Carcinoma; **AND**
  - Patient is in complete or partial response after primary therapy; **AND**
    - Patient has germline or somatic BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test❖; **AND**
      - Used as a single agent; **OR**
      - Used in combination with bevacizumab following primary therapy including bevacizumab; **OR**
    - Patient has BRCA1/2 wild-type or unknown and homologous recombination deficiency (HRD)* as detected by an FDA-approved or CLIA-compliant test❖; **AND**
      - Used in combination with bevacizumab following primary therapy including bevacizumab; **OR**
- Used as maintenance treatment for Clear Cell Carcinoma of the Ovary or Carcinosarcoma (Malignant Mixed Müllerian Tumors); **AND**
  - Patient has germline or somatic BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test❖; **AND**

- Patient has stage II-IV disease and is in complete or partial response after primary therapy; **AND**
  - Used as a single agent; **OR**
  - Used in combination with bevacizumab following primary therapy including bevacizumab; **OR**
- Patient has recurrent disease and is in complete or partial response after at least two prior lines of platinum-based therapy (i.e., platinum sensitive); **AND**
  - Used as a single agent; **AND**
  - Patient has not progressed on prior PARP-inhibitor therapy, if previously received

***Note:** Homologous recombination deficiency (HRD) is defined by either a BRCA 1/2 mutation and/or genomic instability.*

Breast Cancer † ‡ [1,4,5,14]

- Patient has germline BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test❖; **AND**
  - Used as a single agent for recurrent unresectable or metastatic disease OR for inflammatory disease with no response to pre-operative systemic therapy; **AND**
    - Patient has HER2-negative disease; **AND**
      - Patient has hormone receptor (HR)-negative disease (i.e., triple negative breast cancer [TNBC] Ψ); **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 ‡; **OR**
  - Used as a single agent as adjuvant therapy; **AND**
    - Patient has been treated with prior neoadjuvant (preoperative) chemotherapy and has residual disease; **AND**
      - Patient has triple negative breast cancer (TNBC) Ψ; **OR**
      - Patient has hormone receptor (HR)-positive, HER2-negative disease with a clinical stage, pathologic stage, estrogen receptor status, and tumor grade (CSP+EG) score ≥ 3; **OR**
    - Patient received prior adjuvant chemotherapy; **AND**
      - Patient has triple negative breast cancer (TNBC) Ψ and ≥pT2 or ≥pN1; **OR**
      - Patient has hormone receptor (HR)-positive, HER2-negative disease with ≥4 positive lymph nodes

Pancreatic Adenocarcinoma † Φ [1,4,9]

- Patient has germline BRCA1/2 mutated disease as detected by an 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 † ‡ [1,4,12]

- Patient will receive concurrent treatment with a GnRH-analog or has had a bilateral orchiectomy; **AND**
- Patient has metastatic castration-resistant prostate cancer (mCRPC); **AND**
  - Patient has germline or somatic homologous recombination repair (HRR) gene-mutated disease** as detected by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used as a single agent; **AND**
    - Patient does not have a PPP2R2A mutation; **AND**
    - Patient has progressed on prior treatment with androgen receptor-directed therapy (e.g., enzalutamide, abiraterone, darolutamide, apalutamide, etc.); **OR**
  - Patient has germline or somatic BRCA1/2 mutated disease as detected by an FDA-approved or CLIA-compliant test❖; **AND**
    - Used in combination with abiraterone AND prednisone or prednisolone; **AND**
    - Patient has not received prior treatment with abiraterone

***Homologous recombination repair (HRR) gene mutations include BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D or RAD54L.*

Uterine Sarcoma (Uterine Neoplasms) ‡ [4,15]

- Used as a single agent; **AND**
- Used as subsequent therapy for advanced, recurrent, metastatic, or inoperable disease; **AND**
- Patient has leiomyosarcoma (LMS); **AND**
- Patient has BRCA2-altered disease as detected by an FDA-approved or CLIA-compliant test❖

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

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

Ψ ER Scoring Interpretation *(following ER testing by validated IHC assay)*	
Results	**Interpretation**
– 0% – <1% of nuclei stain	– ER-negative

– 1%–10% of nuclei stain	– ER-low–positive*
– >10% of nuclei stain	– ER-positive
**Note: Patients with cancers with ER-low–positive (1%–10%) results are a heterogeneous group with reported biologic behavior often similar to ER-negative cancers; thus, as such these cancers inherently behave aggressively and may be treated similar to triple-negative disease. Individualized consideration of risks versus benefits should be incorporated into decision-making.*	

IV. Renewal Criteria [1,4]

Coverage can be renewed based upon 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, Fallopian Tube, and Primary Peritoneal Cancer (First-Line Maintenance Treatment of Advanced BRCA-mutated Disease)

- Patient has NOT received more than 2 years of treatment

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

Breast Cancer (Adjuvant Treatment)

- Patient has NOT received more than 1 year of treatment

V. Dosage/Administration [1,15]

Indication	Dose
All indications	Administer 300 mg (two 150 mg tablets) orally, twice daily. – First-Line Maintenance Treatment of BRCA-mutated Advanced Epithelial Ovarian/Fallopian Tube/Primary Peritoneal 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. – Adjuvant Treatment of Breast Cancer

	• Continue treatment until disease progression, unacceptable toxicity, or completion of 1 year of treatment. – All Other Indications • Continue treatment until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals (for hospital outpatient use ONLY)

NDC(s):

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

VII. References

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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C56.1	Malignant neoplasm of ovary, right ovary

ICD-10	ICD-10 Description
C56.2	Malignant neoplasm of ovary, left ovary
C56.3	Malignant neoplasm of bilateral ovaries
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
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.3	Personal history of malignant neoplasm of breast
Z85.42	Personal history of malignant neoplasm of other parts of uterus
Z85.43	Personal history of malignant neoplasm of ovary
Z85.46	Personal history of malignant neoplasm of prostate

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

The preceding information is intended for non-Medicare coverage determinations. 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 Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied 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
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
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