

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Lynparza (olaparib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Lynparza (olaparib) capsules Lynparza (olaparib) tablets	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Lynparza (olaparib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of ovarian cancer, including epithelial, ovarian, fallopian tube, or primary peritonea; **AND**
- II. Individual is using for the maintenance treatment of deleterious or suspected deleterious or somatic BRCA-mutated (gBRCAm or sBRCAm) advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
- III. Individual is in complete or partial response to first line platinum based chemotherapy;

OR

- IV. Individual has a diagnosis of ovarian cancer, including epithelial, ovarian, fallopian tube, or primary peritoneal; **AND**
- V. Individual is using for the maintenance treatment of recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer (tablets only); **AND**
- VI. Individual is in complete or partial response to platinum based chemotherapy;

OR

- VII. Individual has a diagnosis of ovarian cancer, including epithelial, ovarian, fallopian tube, or primary peritoneal; **AND**
- VIII. Individual is using for the treatment of deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) advanced ovarian cancer; **AND**
- IX. Individual received prior treatment with 3 or more lines of chemotherapy.

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OR

- X. Individual has a diagnosis of Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer (NCCN): **AND**
- XI. Individual has achieved complete clinical remission (CR) or partial remission (PR) to primary platinum-based chemotherapy; **AND**
- XII. Bevacizumab was used as a component of primary therapy for advanced, recurrent, or metastatic disease; **AND**
- XIII. Individual is using olaparib in combination with bevacizumab; **AND**
- XIV. Individual has a homologous recombination deficiency (HRD) positive status defined by either:
 - A. Deleterious or suspected deleterious BRCA mutation with test results confirmed; **OR**
 - B. Genomic instability with test results confirmed;

OR

- XV. Individual has a diagnosis of breast cancer; **AND**
- XVI. Individual is using for metastatic human epidermal growth factor receptor 2 (HER2)-negative breast cancer; **AND**
- XVII. Individual has mutations in the BRCA gene and test result confirmed; **AND**
- XXVIII. Individual has had prior chemotherapy in neoadjuvant, adjuvant, or metastatic setting (those with hormone receptor (HR) positive breast cancer either had prior endocrine therapy or endocrine therapy was considered inappropriate);

OR

- XIX. Individual has a diagnosis of metastatic pancreatic cancer (Label, NCCN 2A); **AND**
- XX. Individual has no disease progression during > 16 weeks of first-line, platinum based chemotherapy; **AND**
- XXI. Individual is using as maintenance treatment; **AND**
- XXII. Individual has a ECOG status of 0-1: **AND**
- XXIII. Individual has known deleterious germline mutation in BRCA 1 or BRCA 2;

OR

- XXIV. Individual has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC); **AND**
- XXV. Individual has either deleterious or suspected deleterious germline and/or somatic Homologous recombination repair (HRR) mutation which include BRCA1, BRCA2, ATM, BARD1, BRIP1, CDK12, CHEK1, CHEK2, FANCL, PALB2, RAD51B, RAD51C, RAD51D or RAD54L (Label, NCCN1); **AND**
- XXVI. Individual *DOES NOT HAVE* a PPP2R2A mutation (NCCN Prostate Cancer Guideline); **AND**
- XXVII. Disease has progressed following prior treatment with enzalutamide or abiraterone; **AND**
- XXVIII. Individual is using a gonadotropin-releasing hormone (GnRH) analog concurrently or have had a bilateral orchiectomy.

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Note: Do not substitute Lynparza tablets with Lynparza capsules on a milligram-to-milligram basis due to differences in the dosing and bioavailability of each formulation.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. ClinicalTrials.gov [Internet]. Bethesda, MD: National Library of Medicine (US) 2000 Feb 29- . Identifier NCT02184195, Olaparib in gBRCA mutated pancreatic cancer whose disease has not progressed on first line platinum-based chemotherapy (POLO); 2014 Jul 29 [cited 2019 Jul 26];[about 3 screens]. Available from: <https://clinicaltrials.gov/ct2/show/NCT02184195?term=NCT02184195&rank=1>. Accessed: January 27, 2020.
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 27, 2020.
4. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
5. Golan T, Hammel P, Reni, M, et al. Maintenance Olaparib for Germline BRCA-Mutated Metastatic Pancreatic Cancer. N Engl J Med. 2019 July 25; 381(4):317-327. Available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6810605/pdf/nihms-1536856.pdf>. Accessed: January 27, 2020.
6. Kaufman B, Shapira-Frommer R, Schmutzler RK, et al. Olaparib monotherapy in patients with advanced cancer and a germline BRCA1/2 mutation. J Clin Oncol 2015 Jan 20;33(3):244-50. Available at: <https://ascopubs.org/doi/pdf/10.1200/JCO.2014.56.2728>. Accessed: October 24, 2019
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 27, 2020.
 - a. Prostate Cancer. V2.2020. Revised May 21, 2020.
 - b. Ovarian Cancer. V1.2020. Revised March 11, 2020.
9. Ray-Coquard I, Oautier P, Pignata S, et al. Olaparib plus Bevacizumab as First-Line Maintenance in Ovarian Cancer. N Engl J Med 2019;381(25):2416-2428. Available at <https://www.nejm.org/doi/pdf/10.1056/NEJMoa1911361?articleTools=true> . Accessed April 20, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.