Lynparza (olaparib)

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

Medications	Quantity Limit
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 recurrent or advanced ovarian cancer, including epithelial, ovarian, or primary peritoneal (Label, NCCN 1, 2A); **AND**
   A. Individual is using as a single agent for maintenance therapy; **AND**
   B. Individual meets one of the following:
      1. Individual has a germline or somatic BRCA mutation-positive disease; **AND**
      2. Individual is in complete or partial response to first-line platinum-based chemotherapy regimen;
         OR
      3. Individual is in complete or partial response after platinum-based chemotherapy regimens.

OR

II. Individual has a diagnosis of advanced ovarian cancer, including epithelial, ovarian, or primary peritoneal (Label, NCCN 1, 2A); **AND**
   A. Individual is using in combination with bevacizumab (or its biosimilars); **AND**
   B. Individual meets one of the following:
      1. Individual is using for maintenance therapy; **AND**
      2. Individual has homologous recombination deficiency (HRD)-positive disease; **AND**
      3. Individual is in complete or partial response to a first-line platinum-based chemotherapy regimen;
         OR
      4. Individual has germline or somatic BRCA mutation-positive disease; **AND**
      5. Individual is in complete or partial response after primary therapy including bevacizumab (or its biosimilars);

OR

III. Individual has a diagnosis of high-risk early breast cancer; **AND**
   A. Using as a single agent for adjuvant therapy; **AND**
   B. Has one of the following:
      1. HER2-negative disease with deleterious or suspected gBRCAm (Label, NCCN 1, 2A); **AND**
      2. Previously been treated with chemotherapy;
      OR
      3. Triple-negative breast cancer disease (NCCN 1);

OR

IV. Individual has a diagnosis of either gBRCAm metastatic or recurrent breast cancer; **AND**
   A. Using as a single agent; **AND**
   B. Has one of the following:
      1. HER2-positive disease (NCCN 2A); **OR**
      2. HER2-negative and previously treated with chemotherapy in the neoadjuvant or metastatic setting; **OR**
      3. HER2-negative and hormone receptor (HR)-positive disease and previously treated with chemotherapy in the adjuvant setting with visceral crisis, prior endocrine therapy, or considered inappropriate for endocrine therapy (Label, NCCN 1, 2A); **OR**
      4. Triple-negative breast cancer disease (NCCN 1);

OR

V. Individual has a diagnosis of metastatic pancreatic cancer (Label, NCCN 2A); **AND**
   A. The disease has no progressed 16 weeks with a first-line, platinum-based chemotherapy; **AND**
   B. Individual is using as maintenance treatment; **AND**
   C. Individual has a ECOG status of 0-2; **AND**
   D. Individual has known deleterious germline mutation in BRCA; **AND**
   E. Using as a single agent;

OR

VI. Individual has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (Label, NCCN 1); **AND**
   A. 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**
   B. Disease has progressed following prior treatment with androgen receptor-directed therapies including but not limited to abiraterone, Xtandi, Nubeqa, or Erleada; **AND**
   C. Individual is using a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix) concurrently or has had a bilateral orchiectomy; **AND**
   D. Individual is using as a single agent;

OR

VII. Individual has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC); **AND**
   A. Individual has deleterious or suspected deleterious BRCA-mutation (BRCAm); **AND**
   B. Individual is using in combination with abiraterone acetate; **AND**
   C. Individual is using in combination with prednisone or prednisolone;

OR

VIII. Individual has a diagnosis of advanced, recurrent, or metastatic uterine neoplasms (NCCN 2A);
   A. Individual is using as a single agent; **AND**
   B. Individual has germline or somatic BRCA mutation: **AND**
   C. Individual is using as second-line or subsequent therapy.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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: June 28, 2023
3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm. Accessed: June 28, 2023
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: June 28, 2023
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: June 28, 2023
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on June 28, 2023.
    a. Breast Cancer. V4.2023. Revised March 23, 2023
    b. Pancreatic Adenocarcinoma. V2.2023. Revised June 19, 2023.
    c. Prostate Cancer. V1.2023. Revised September 16, 2022.
    d. Ovarian Cancer. V2.2023. Revised June 2, 2023
    e. Uterine Neoplasms. V2.2023. Revised April 28, 2023.
9. Pan M, Ganjoo K, Karam A. Rapid Response of a BRCA2/TP53/PTEN-Deleted Metastatic Uterine Leiomyosarcoma to Olaparib: A Case Report Perm J 2021;25:20.251
10. 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 June 28, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.