Rubraca (rucaparib)

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

Medications	Quantity Limit
Rubraca (rucaparib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Rubraca (rucaparib) may be approved if the following criteria are met:

I. Individual has one of the following diagnosis (Label, NCCN 1, 2A):
   A. Recurrent ovarian cancer, including, epithelial, fallopian tube, or primary peritoneal cancer;
      OR
   B. Deleterious BRCA mutation associated with recurrent ovarian cancer, including epithelial, fallopian tube, or primary peritoneal cancer;

AND

II. Individual has a complete or partial response to platinum-based chemotherapy; **AND**
III. Individual is receiving as maintenance therapy; **AND**
IV. Individual is using as a single agent;

OR

V. Individual has a diagnosis of ovarian cancer, including epithelial, ovarian, or primary peritoneal (NCCN 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 following primary therapy including bevacizumab;
         OR
      3. Individual is in complete or partial response following primary therapy;

OR

VI. Individual has a diagnosis of pancreatic adenocarcinoma (NCCN 2A); **AND**
   A. Individual is using for metastatic disease with germline or somatic BRCA 1/2 or PALB2 mutations; **AND**
   B. Individual is using as a single agent for maintenance therapy; **AND**
   C. Individual has an ECOG performance status of 0-1; **AND**
   D. Individual has no disease progression following the most recent platinum-based chemotherapy;

OR

VII. Individual has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) with a deleterious BRCA mutation (germline and/or somatic) (Label, NCCN 2A); **AND**
   A. Individual had been treated with androgen-receptor directed therapy including but not limited to abiraterone, Xtandi, Nubeqa, or Erleada and a taxane-based chemotherapy; **AND**
   B. Individual is using a gonadotropin-releasing hormone (GnRH) analog (e.g. Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix) concurrently or have had a bilateral orchiectomy; **AND**
   C. Individual is using as a single agent;

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. 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
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. 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.
6. 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
7. 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.