

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

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 a diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
- II. Individual has a deleterious germline and/or somatic BRCA mutation (test results confirmed); **AND**
- III. Individual has received at least two prior chemotherapy treatments;

OR

- IV. Individual has a diagnosis of recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer; **AND**
- V. Individual has a complete or partial response to platinum-based chemotherapy; **AND**
- VI. Individual is receiving as maintenance therapy (Label, NCCN 2A);

OR

- VII. Individual has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) with a deleterious BRCA mutation (germline and/or somatic); **AND**
- VIII. Individual had been treated with androgen-receptor directed therapy and a taxane-based chemotherapy; **AND**
- IX. 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.

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Applicable	X	X	X	X	X	X

Note:

This FDA approval is under accelerated approval and continued approval for this indication may be contingent upon verification in confirmatory trials. Monitor patients for hematological toxicity at baseline and monthly thereafter. Discontinue if Myelodysplastic Syndrome/Acute Myeloid Leukemia is confirmed.

Key References:

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3. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: July 21, 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: July 21, 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: July 21, 2020
7. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
8. NCCN Clinical Practice Guidelines in Oncology™. © 2020 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on July 21, 2020
 - a. Pancreatic Adenocarcinoma. V1.2020. Revised November 26, 2019.
 - 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 July 21, 2020

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