

Clinical Policy Title:	rucaparib
Policy Number:	RxA.463
Drug(s) Applied:	Rubraca®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of Business

Background

Rucaparib (Rubraca®) is a poly (ADP-ribose) polymerase (PARP) inhibitor.

Rubraca® is indicated:

- Ovarian cancer:
 - For the treatment of adult patients with deleterious BRCA mutation (germline and/or somatic)-associated epithelial ovarian, fallopian tube, or primary peritoneal cancer who have been treated with two or more chemotherapies. Select patients for therapy based on an FDA approved companion diagnostic for Rubraca.
 - For the maintenance treatment of adult patients with recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- Prostate Cancer:
 - For the treatment of adult patients with a deleterious BRCA mutation (germline and/or somatic)-associated metastatic castration-resistant prostate cancer (mCRPC) who have been treated with androgen receptor-directed therapy and a taxane-based chemotherapy.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Rucaparib (Rubraca®)	Ovarian cancer	600 mg PO BID	1200 mg/day
	Prostate Cancer	600 mg PO BID With concomitant gonadotropin-releasing hormone (GnRH) analog or should have had bilateral orchiectomy.	1200 mg/day

Dosage Forms

- Tablets: 200 mg, 250 mg, and 300 mg

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Ovarian Cancer (must meet all):

1. Diagnosis of epithelial ovarian, fallopian tube, or primary peritoneal cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. One of the following (a or b):
 - a. Both i and ii:
 - i. Deleterious or suspected deleterious germline and/or somatic BRCA mutation;
 - ii. Failure of \geq 2 lines of chemotherapy, unless contraindicated or clinically significant adverse effects are experienced;
 - b. Completed 2 platinum-based chemotherapy regimens and is in a complete or partial response;
5. Request meets one of the following (a or b):
 - a. Dose does not exceed 1,200 mg/day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration

Commercial: 6 months

Medicaid: 6 months

B. Prostate Cancer (must meet all):

1. Diagnosis of mCRPC;
2. Prescribed by or in consultation with an oncologist;
3. Age \geq 18 years;
4. Request meets one of the following (a or b):
 - a. Concomitant therapy gonadotropin-releasing hormone (GnRH) analog;
 - b. Had bilateral orchiectomy;
5. Patient has a pathogenic BRCA1 or BRCA2 mutation (germline and/or somatic);
6. Failure of androgen receptor-directed therapy, unless contraindicated or clinically significant adverse effects are experienced;
7. Failure of a taxane-based chemotherapy, unless patient is not fit for chemotherapy;
8. Request meets one of the following (a or b):
 - a. Dose does not exceed 1,200 mg/day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration

Commercial: 6 months

Medicaid: 6 months

II. Continued Therapy Approval

A. Ovarian Cancer (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance, or documentation supports that member is currently receiving Rubraca for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
 - a. 1,200 mg/day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration

Medicaid: 12 months

Commercial: 12 months

B. Prostate Cancer (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy.
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed (a or b):
 - a. 1,200 mg/day;
 - b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval Duration

Commercial: 12 months

Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

BRCA: breast cancer susceptibility gene

FDA: Food and Drug Administration

PARP: poly (ADP-ribose) polymerase

mCRPC: metastatic castration-resistant prostate cancer

APPENDIX B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Ovarian Cancer		
Alimta® (pemetrexed)	Various	Varies
Alkeran® (melphalan)	Various	Varies
Avastin® (bevacizumab)	Various	Varies
carboplatin (Paraplatin®)	Various	Varies

cisplatin	Various	Varies
cyclophosphamide	Various	Varies
docetaxel (Taxotere®)	Various	Varies
doxorubicin (Doxil®, Adriamycin®)	Various	Varies
etoposide	Various	Varies
gemcitabine	Various	Varies
ifosfamide (Ifex®)	Various	Varies
irinotecan (Camptosar®)	Various	Varies
oxaliplatin	Various	Varies
topotecan (Hycamtin®)	Various	Varies

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
 - None
- Boxed Warning(s):
 - None

APPENDIX D: General Information

- None

References

1. Rubraca Prescribing Information. Boulder, CO: Clovis Oncology, Inc.; May 2020. Available at: <http://clovisoncology.com/pdfs/RubracaUSPI.pdf>. Accessed July 22, 2020.
2. Rucaparib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 23, 2020.
3. National Comprehensive Cancer Network. Prostate cancer Version 2.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 23, 2020.
4. National Comprehensive Cancer Network. Ovarian cancer Version 1.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed July 23, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated. 2. Line of Business Policy Applies to was update to all lines of business. 3. Background was updated. 4. Dosing information updated to	07/23/2020	09/14/2020

<p>include prostate cancer dosing regimen.</p> <ol style="list-style-type: none">5. Initial Approval criteria updated to include criteria for prostate cancer.6. Continued Therapy criteria updated to include prostate cancer continuation criteria.7. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..."8. Initial Approval criteria: Commercial approval duration was updated from length of benefit to 6 months for Ovarian cancer.9. Continued Approval criteria: Commercial approval duration was updated from length of benefit to 12 months for Ovarian cancer.10. APPENDIX B was updated: brand Platinol-AQ®, Cytosan®, Vepesid®, Gemzar®, Eloxatin®, Hexalen® were removed due to drug discontinuation.11. References were updated.		
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