Clinical Policy Title:	rucaparib
Policy Number:	RxA.463
Drug(s) Applied:	Rubraca®
Original Policy Date:	03/06/2020
Last Review Date:	09/14/2021
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 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.
  - Select patients for therapy based on an FDA-approved companion diagnostic for Rubraca®.
  - This indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
rucaparib (Rubraca®)	Ovarian cancer	600 mg orally twice daily	1200 mg/day
	Prostate Cancer	600 mg orally twice daily 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

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. The provision of provider samples does not guarantee coverage under the terms of the pharmacy benefit administered by RxAdvance. All criteria for initial approval must be met in order to obtain coverage.

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 ≥ 18 years;
4. Member meets 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 ≥ 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 ≥18 years;
4. Request meets one of the following (a or b):
   a. Concomitant therapy with a 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. Member is 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. Member is 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. Continue androgen deprivation therapy (ADT) to maintain castrate levels of serum testosterone (<50 ng/dL);
4. If request is for a dose increase, new dose does not exceed (a or b):
   a. 1,200 mg/day;

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
ADT: androgen deprivation therapy
MDS: Myelodysplastic Syndrome
AML: Acute Myeloid Leukemia

APPENDIX B: Therapeutic Alternatives
Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Ovarian Cancer		
Alimta®	Various	Varies
melphalan (Alkeran®)	Various	Varies
bevacizumab (Avastin®)	Various	Varies
carboplatin (Paraplatin®)	Various	Varies
cisplatin	Various	Varies
cyclophosphamide	Various	Varies
docetaxel (Taxotere®)	Various	Varies
doxorubicin (Doxil®, Adriamycin®)	Various	Varies

Drug Name	Dosing Regimen	Dose Limit/Maximum Dose
Ovarian Cancer		
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 generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic name when the drug is available by generic only.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None reported.

- Boxed Warning(s):
  - None reported.

APPENDIX D: General Information

- Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML): MDS/AML occurred in patients exposed to Rubraca®, and some cases were fatal. Monitor patients for hematological toxicity at baseline and monthly thereafter. Interrupt or reduce the dose based on severity of reaction. Discontinue if MDS/AML is confirmed.
- Embryo-Fetal Toxicity: Rubraca® can cause fetal harm. Advise of the potential risk to a fetus and to use effective contraception.

References

1. Rubraca® Prescribing Information. Boulder, CO: Clovis Oncology, Inc; October 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/209115s008lbl.pdf . Accessed July 1, 2021.
2. Rucaparib. In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed July 1, 2021.
3. National Comprehensive Cancer Network. Prostate cancer Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed July 1, 2021.
4. National Comprehensive Cancer Network. Ovarian cancer Version 1.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed July 1, 2021.

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.	07/23/2020	09/14/2020

3. Background was updated. 4. Dosing information updated to include prostate cancer dosing regimen. 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®, Cytoxan®, Vepesid®, Gemzar®, Eloxatin®, Hexalen® were removed due to drug discontinuation. 11. References were updated.		
Policy was reviewed: 1. Statement about provider sample ‘‘The provision of provider samples does not guarantee coverage…” was added to Clinical Policy. 2. Continued Therapy Approval Criteria II.A.1 and II.B.1 were rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. Continued Therapy Approval Criteria II.B.3 was updated to include “Continue androgen deprivation therapy (ADT) to maintain castrate levels…”. 4. Appendix A was updated to include abbreviations ADT, MDS, and AML. 5. Therapeutic Alternatives verbiage was updated to "Below are suggested therapeutic alternatives based on clinical guidance.." 6. Appendix B: Therapeutic Alternatives was updated to remove unavailable drug pemetrexed. 7. Statement about drug listing format in Appendix B is updated to "Therapeutic alternatives are listed as generic (Brand name®) when the drug is available by both generic and brand, Brand name® when the drug is available by brand only and generic	7/1/2021	09/14/2021

name when the drug is available by generic only". 8. Appendix D was updated to include warnings and precautions, “Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML)…” and “Embryo-Fetal Toxicity…”. 9. References were reviewed and updated.		