Clinical Policy Title:	rucaparib
Policy Number:	RxA.463
Drug(s) Applied:	Rubraca®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

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 ≥ 18 years;
4. Prescribed as a single agent;
5. Member has not previously received a PARP inhibitor (e.g., Lynparza®, Talzenna®, Zejula®) ;
6. Member meets one of the following (a or b):*
   a. Both i and ii :
      i. Documentation of deleterious or suspected deleterious BRCA mutation;
      ii. Completed platinum-based chemotherapy and is in a complete or partial response;
   b. Both i and ii:
      i. Newly diagnosed stage II-IV disease;
      ii. Completed first-line platinum-based chemotherapy regimen and is in a complete or partial response;
      *Prior authorization may be required.
7. 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).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

B. Prostate Cancer (must meet all)**:**

1. Diagnosis of mCRPC;
2. Prescribed by or in consultation with an oncologist or a urologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):
   a. Concomitant therapy with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin);
   b. Had bilateral orchiectomy;

5. Patient has a pathogenic BRCA1 or BRCA2 mutation (germline and/or somatic);
6. Trial and failure of androgen receptor-directed therapy (e.g., abiraterone, Xtandi®, Erleada®, or Nubeqa®), unless contraindicated or clinically significant adverse effects are experienced;
7. Trial and failure of a taxane-based chemotherapy (e.g., docetaxel), 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).

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

C. Pancreatic Adenocarcinoma (off-label) (must meet all)**:**
1. Diagnosis of pancreatic adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥18 years;
4. Request will be used as maintenance therapy for metastatic disease as a single agent;
5. Member has a germline or somatic BRCA1/2 or PALB2 mutations;
6. Member does not have a disease progression (after at least 4-6 months of chemotherapy, assuming acceptable tolerance) following the most recent platinum-based chemotherapy;
7. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

D. Uterine Sarcoma (off-label) (must meet all)**:**
1. Diagnosis of advanced, recurrent/metastatic, or inoperable uterine sarcoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥18 years;
4. Request will be used as single-agent second-line therapy;
5. Member has a BRCA altered uterine leiomyosarcoma (uLMS);
6. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).*

   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval Duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

A. All Indications in Section I (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).*
*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Medicaid: 12 months
Commercial: 12 months

References

1. National Comprehensive Cancer Network. Prostate cancer Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed June 30, 2023.
2. National Comprehensive Cancer Network. Ovarian cancer Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed June 30, 2023.
3. National Comprehensive Cancer Network. Uterine Neoplasms Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed June 30, 2023.
4. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed June 30, 2023.

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. Initial Approval criteria updated to include criteria for prostate cancer. 4. Continued Therapy criteria updated to include prostate cancer continuation criteria. 5. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 6. Initial Approval criteria: Commercial approval duration was updated from length of benefit to 6 months for Ovarian cancer. 7. Continued Approval criteria: Commercial approval duration was updated from length of benefit to 12 months for Ovarian cancer. 8. References were updated.	07/23/2020	09/14/2020
Policy was reviewed: 1. 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...". 2. Continued Therapy Approval Criteria II.B.3 was updated to include “Continue androgen deprivation therapy (ADT) to maintain castrate	07/01/2021	09/14/2021

levels…”. 3. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A.4: Updated to include new dosing criteria Prescribed as a single agent. 2. Initial Approval Criteria, I.A.5.a: Updated to remove 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; 3. Initial Approval Criteria, I.A.6: Updated to include new trial and failure criteria Member has not previously received a PARP inhibitor (e.g., Lynparza®, Talzenna®, Zejula®). 4. Initial Approval Criteria, I.B.2: Updated prescriber criteria from Prescribed by or in consultation with an oncologist to Prescribed by or in consultation with an oncologist or a urologist. 5. Initial Approval Criteria, I.C: Updated to include approval criteria for indication, Pancreatic Adenocarcinoma. 6. Initial Approval Criteria, I.D: Updated to include approval criteria for indication, Uterine Sarcoma. 7. Continued Therapy Approval Criteria, II.A and II.B: Updated to remove Ovarian cancer and Prostate cancer and merged as II.A. All indications in Section I. 8. References were reviewed and updated.	04/04/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.5: Updated to remove prior trial and failure criteria Member has completed 2 platinum-based chemotherapy regimens and is in a complete or partial response. 2. Initial Approval Criteria, I.A.6: Updated to include new criteria pertaining to indication Member meets one of the following (a or b):* a. Both i and ii: i. Documentation of deleterious or suspected deleterious BRCA mutation;	06/30/2023	07/13/2023

ii. Completed platinum-based chemotherapy and is in a complete or partial response; b. Both i and ii: i. Newly diagnosed stage II-IV disease; ii. Completed first-line platinum-based chemotherapy regimen and is in a complete or partial response. 3. Initial Approval Criteria, I.D.1: Updated indication from Diagnosis uterine sarcoma to Diagnosis of advanced, recurrent/metastatic, or inoperable uterine sarcoma. 4. Initial approval durations updated from 6 months to 12 months for all indications and lines of business. 5. References were reviewed and updated.		
Policy was reviewed.	10/19/2023	10/19/2023