

Clinical Policy Title:	rucaparib
Policy Number:	RxA.463
Drug(s) Applied:	Rubraca®
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
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. Member has a deleterious BRCA mutation (germline or somatic);
3. Member has had a complete or partial response to platinum-based chemotherapy.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Prostate Cancer (must meet all):

1. Diagnosis of metastatic castration-resistant prostate cancer);
2. Member has a deleterious BRCA mutation (germline or somatic);
3. Previous treatment with androgen receptor-directed therapy and a taxane-based chemotherapy;
4. Trial and failure of androgen receptor-directed therapy (e.g., abiraterone, Xtandi®, Erleada®, or Nubeqa®), unless contraindicated or clinically significant adverse effects are experienced.
5. Trial and failure of a taxane-based chemotherapy (e.g., docetaxel), unless contraindicated or clinically significant adverse events are experienced.

Approval Duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network. Prostate cancer Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed March 24, 2025.
2. National Comprehensive Cancer Network. Ovarian cancer Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed March 24, 2025.
3. National Comprehensive Cancer Network. Uterine Neoplasms Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed March 24, 2025.

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.

4. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma. Version 3.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed March 24, 2025.
5. National Comprehensive Cancer Network. Epithelial Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer. Version 1.2025. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed March 24, 2025.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	02/2020	03/06/2020
Policy was reviewed: <ol style="list-style-type: none"> 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: <ol style="list-style-type: none"> 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 levels..." 3. References were reviewed and updated. 	07/01/2021	09/14/2021
Policy was reviewed: <ol style="list-style-type: none"> 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 <ol style="list-style-type: none"> i. Deleterious or suspected deleterious germline and/or somatic BRCA mutation; 	04/04/2022	07/18/2022

<ul style="list-style-type: none"> 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. 		
<p>Policy was reviewed:</p> <ul style="list-style-type: none"> 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):* <ul style="list-style-type: none"> a. Both i and ii: <ul style="list-style-type: none"> 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: <ul style="list-style-type: none"> 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 	<p>06/30/2023</p>	<p>07/13/2023</p>

<p>Diagnosis of advanced, recurrent/metastatic, or inoperable uterine sarcoma.</p> <ol style="list-style-type: none"> 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
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Removed prescribed as a single agent, 2. Removed prior therapy with a PARP inhibitor. 3. Removed use as a single agent. 4. Removed specialist and age. 5. Removed dosing. 6. Updated look back period of 120 days for continued approval. 	09/23/2024	
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. References were reviewed and updated. 	03/24/2025	04/10/2025
Policy was reviewed.	12/11/2025	12/11/2025