Clinical Policy Title:	olaparib
Policy Number:	RxA.401
Drug(s) Applied:	Lynparza®
Original Policy Date:	03/06/2020
Last Review Date:	01/01/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Epithelial ovarian, fallopian tube, or primary peritoneal cancer (must meet all):

1. Diagnosis of one of the following: epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer
2. Prescribed by or in consultation with an oncologist.

Approval Duration

All Lines of Business (except Medicare): 12 months

B. Breast Cancer (must meet all):

1. Diagnosis of breast cancer;
2. Member meets one of the following (a or b):
   a. Adjuvant Treatment of Germline BRCA-mutated HER2-negative high risk early breast cancer
   b. Germline BRCA-mutated HER2-negative Metastatic Breast Cancer
3. Prescribed by or in consultation with an oncologist.

Approval Duration

All Lines of Business (except Medicare): 12 months

C. Pancreatic Cancer (must meet all):

1. Diagnosis of pancreatic adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Received > 16 weeks of platinum-based chemotherapy with no disease progression.

Approval Duration

All Lines of Business (except Medicare): 12 months

D. Prostate Cancer (must meet all):

1. Diagnosis of the following (a or b):
   a. HRR gene mutated castration-resistant prostate cancer
   b. BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer;
2. Prescribed by or in consultation with an oncologist;
3. For HRR gene mutated castration-resistant prostate cancer:
   a. Continued disease progression following prior treatment with enzalutamide or abiraterone
4. For BRCA-mutated (BRCAm) mCRPC:
   a. Used in combination with abiraterone and one of the following: prednisone or prednisolone.

Approval Duration
All Lines of Business (except Medicare): 12 months

E. Uterine Sarcoma (Off -Label) (must meet all):
1. Diagnosis of Uterine Sarcoma;
2. Prescribed as second-line therapyagent;
3. Prescribed by or in consultation with an oncologist;

Approval Duration
All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all):
1. Member is currently receiving or has been treated with this medication within the past 90 days, excluding manufacturer samples.

Approval Duration
All Lines of Business (except Medicare): 12 months

References

1. National Comprehensive Cancer Network Guidelines. Breast Cancer Version 4.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed December 14, 2023.
2. National Comprehensive Cancer Network Guidelines. Ovarian Cancer Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed December 14, 2023.
3. National Comprehensive Cancer Network Guidelines. Pancreatic Adenocarcinoma Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Accessed December 14, 2023.
4. National Comprehensive Cancer Network Guidelines. Prostate Cancer Version 1.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/prostate.pdf. Accessed December 14, 2023.
5. National Comprehensive Cancer Network Guidelines. Uterine Neoplasms. Version 2.2023. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed December 14, 2023.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Clinical Policy Title was updated 2. Drug(s) Applied was updated 3. Line of Business Policy Applies to was updated 4. Continued Therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance..." 5. Commercial approval duration and Medicaid/HIM approval duration updated. 6. Added new indication for treatment of gBRCAm metastatic pancreatic adenocarcinoma and germline or somatic homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) 7. Updated Initial Approval Criteria for Ovarian Cancer to include first line maintenance treatment of HRD-	06/19/2020	09/14/2020

positive advanced ovarian cancer in combination with bevacizumab 8. References were updated		
Policy was reviewed: 1. Initial Approval Criteria I.B.5 was updated to include “Patients with hormone receptor (HR)-positive breast cancer…” 2. Continued Therapy criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. Initial Approval Criteria and Continued Therapy Approval Criteria was updated to remove HIM approval duration. 4. References were reviewed and updated.	06/01/2021	09/14/2021
Policy was reviewed: 1. Initial Approval Criteria I.B.1.c: Updated to add adjuvant treatment of germline BRCA-mutated HER2 negative high risk early breast cancer. 2. Initial Approval Criteria I.B: Updated and consolidated diagnostic criteria from diagnosis of breast cancer based on new indication for adjuvant treatment for early breast cancer. 3. Initial Approval Criteria I.D.1: Updated from “pancreatic cancer” to “metastatic castration-resistant prostate cancer (mCRPC)”. 4. References were reviewed and updated.	06/14/2022	07/18/2022
Policy was reviewed: 1. Initial Approval Criteria, I.A.4.a: Updated to remove prior criteria pertaining to indication Ovarian Cancer Both i and ii: i. Documentation of deleterious or suspected deleterious germline BRCA mutation; ii. Trial and failure of ≥ 3 lines of platinum-based chemotherapy, unless contraindicated or clinically significant adverse effects are experienced; 2. Initial Approval Criteria, I.A.4.b: Updated to remove diagnostic criteria "Completed ≥ 2 platinum-based chemotherapy regimens and is in a complete or partial response." 3. Initial Approval Criteria, I.A.4.a: Updated diagnostic criteria from Documentation of a deleterious or suspected deleterious germline or somatic BRCA-mutation to Documentation of a deleterious or suspected deleterious germline or somatic BRCA-	06/28/2023	07/13/2023

mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx); 4. Initial Approval Criteria, I.A.4.b: Updated diagnostic criteria from All i, ii, and iii: i. Cancer is associated with homologous recombination deficiency (HRD)-positive status defined by deleterious or suspected deleterious germline BRCA mutation and/or genomic instability; ii. In complete or partial response to first-line platinum-based chemotherapy; iii. Prescribed in combination with bevacizumab; to Both i and ii: i. Disease is associated with homologous recombination deficiency (HRD)-positive status defined by one of the following (1 or 2): 1. Deleterious or suspected deleterious germline BRCA mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx); 2. Genomic instability; ii. Both of the following (1 and 2): 1. Completed a bevacizumab- and platinum-based chemotherapy regimen as first-line therapy, and is in a complete or partial response; 2. Prescribed in combination with bevacizumab; 5. Initial Approval Criteria, I.A, I.B, I.C & I.D: Updated Approval duration from 6 to 12 months for Commercial. 6. Initial Approval Criteria, I.B.1.a: Updated diagnostic criteria from Deleterious or suspected deleterious germline BRCA to Deleterious or suspected deleterious germline BRCA 1/2 mutations as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx). 7. Initial Approval Criteria, I.B.1.b: Updated to remove prior criteria pertaining to indication Breast Cancer, Previously treated with neoadjuvant or adjuvant chemotherapy, or metastatic setting; 8. Initial Approval Criteria, I.B.1.c: Updated to remove prior criteria pertaining to indication Breast Cancer, Adjuvant treatment of germline BRCA-mutated HER2 negative high risk early breast cancer. 9. Initial Approval Criteria, I.B.1.c: Updated to include diagnostic criteria High risk, metastatic or recurrent.		

10. Initial Approval Criteria, I.B.1.e: Updated to remove prior criteria pertaining to indication Breast Cancer, Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior or concurrent endocrine therapy or be considered inappropriate for endocrine therapy and have CPS + EG score ≥ 3; 11. Initial Approval Criteria, I.C.4: Updated age criteria from Disease has mutations in the BRCA genes to Deleterious or suspected deleterious germline BRCA mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx). 12. Initial Approval Criteria, I.D.4: Updated diagnosis criteria from Disease has mutations in the HRR genes to Member meets one of the following (a or b): a. Deleterious or suspected deleterious germline or somatic HRR gene mutation as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx). b. Deleterious or suspected deleterious BRCA-mutated (BRCAm) metastatic castration-resistant prostate cancer (mCRPC) as confirmed on a CLIA approved diagnostic test (e.g., Foundation One CDx or BRAC Analysis CDx). 13. Initial Approval Criteria, I.D.5.b: Updated to include new combination criteria, In combination with abiraterone and prednisone or prednisolone; 14. Initial Approval Criteria, I.E: Updated to include approval criteria for indication, Uterine Sarcoma. 15. References were reviewed and updated.		
Policy was reviewed: 1. Removed prior age criteria. 2. Removed diagnostic criteria for epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer. 3. Removed requirement for confirmation of Deleterious or suspected deleterious germline BRCA mutations for Pancreatic Cancer and Prostate Cancer. 4. Removed requirement of use as single agent for Uterine sarcoma. 5. Removed requirement for confirmation of Deleterious or suspected deleterious germline or somatic HRR gene mutations for Prostate Cancer. 6. Updated approval duration. 7. Removed reauthorization requirement for positive	12/14/2023	01/01/2024

response to therapy. 8. References were reviewed and updated.		