Clinical Policy: Olaparib (Lynparza)

Reference Number: HIM.PA.SP34
Effective Date: 08.01.17
Last Review Date: 11.17
Line of Business: Health Insurance Marketplace

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description

Olaparib (Lynparza®) is a poly (ADP-ribose) polymerase (PARP) inhibitor.

FDA Approved Indication(s)

Lynparza is indicated:

- For the treatment of adult patients with deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy. Select patients for therapy based on an FDA-approved companion diagnostic for Lynparza.
- 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.

Policy/Criteria

Provider must submit documentation (which may include office chart notes and lab results) 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. Age ≥ 18 years;
3. One of the following (a or b):
   a. Both i and ii:
      i. Documentation of deleterious or suspected deleterious germline BRCA-mutation as detected by an FDA-approved test (e.g., BRACAnalysis CDx);
      ii. Failure of ≥ 3 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;
4. Dose does not exceed (a or b):
   a. Capsules: 800 mg/day;
   b. Tablets: 600 mg/day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Ovarian Cancer (must meet all)**:**

1. Currently receiving medication via Centene benefit or documentation supports that member is currently receiving Lynparza for ovarian cancer and has received this medication for at least 30 days;
2. Member is responding positively to therapy (e.g., no disease progression, no significant toxicity);
3. If request is for a dose increase, new dose does not exceed (a or b):
   a. Capsules: 800 mg/day;
   b. Tablets: 600 mg/day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to HIM.PHAR.21 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – HIM.PHAR.21 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ADP: adenosine diphosphate
AML: acute myeloid leukemia
BRCA: breast cancer gene
FDA: Food and Drug Administration
gBRCAm: mutations in the BRCA genes
MDS: myelodysplastic syndrome
NCCN: National Comprehensive Cancer Network
PARP: poly (ADP-ribose) polymerase

Appendix B: General Information

- NCCN recommended use:
  - Preferred single-agent therapy in patients with BRCA mutated genes for persistent disease or recurrence following three or more lines of therapy.
  - Maintenance therapy for patients with platinum-sensitive disease who have completed two or more lines of platinum-based therapy and are in a complete or partial response
- Myelodysplastic syndrome/acute myeloid leukemia (MDS/AML) have been confirmed in patients treated with Lynparza. The majority of the cases (17 of 22) were fatal. If MDS/AML is confirmed, discontinue Lynparza.
- The FDA approved Lynparza with a genetic test called BRACAnalysis CDx, a companion diagnostic that will detect the presence of mutations in the BRCA genes

(gBRCAm) in blood samples from patients with ovarian cancer. It is is available at http://www.fda.gov/companiondiagnostics.

V. References

1. Lynparza Prescribing Information. Wilmington, DE: AstraZeneca Pharmaceuticals LP. August 2017. Available at https://www.lynparza.com/. Accessed September 2017.
2. National Comprehensive Cancer Network. Ovarian Cancer Version 3.2017. Available at: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed September 8, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created.	04.17	08.17
Added new indication for maintenance treatment of ovarian cancer. Added age requirement as safety and efficacy have not been established in pediatric populations. Modified Section II to allow continuity of care.	10.03.17	11.17

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan

retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.