Reference number
1810-A

SPECIALTY GUIDELINE MANAGEMENT

LYNPARZA (olaparib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications

A. Ovarian Cancer
   1. Maintenance Treatment of Recurrent Ovarian Cancer
      Lynparza is indicated 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.
   2. Advanced *gBRCA*-mutated Ovarian Cancer After 3 or More Lines of Chemotherapy
      Lynparza is indicated for the treatment of adult patients with deleterious or suspected deleterious germline *BRCA*-mutated (*gBRCAm*) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.
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B. Breast Cancer
   Germline BRCA-mutated HER2-negative metastatic breast cancer
   Lynparza is indicated in patients with deleterious or suspected deleterious *gBRCAm*, HER2-negative metastatic breast cancer, who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy.

Compendial uses

Recurrent or metastatic HER2-negative, BRCA 1/2 positive disease that is hormone receptor-negative or hormone receptor-positive and endocrine therapy refractory

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

A. Ovarian Cancer
   Authorization of 12 months may be granted for the treatment of advanced or recurrent ovarian cancer when the member has received prior treatment with chemotherapy.

B. Breast Cancer
   Authorization of 12 months may be granted for the treatment of human epidermal growth factor receptor 2 (HER2)-negative recurrent or metastatic breast cancer in members with deleterious or suspected deleterious germline BRCA mutations when the member has received prior treatment with chemotherapy or endocrine therapy.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Lynparza™ Capsules [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; October 2017.
2. Lynparza® Tablets [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2018.
3. The NCCN Drugs & Biologics Compendium® © 2018 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 19, 2018.
4. The NCCN Clinical Practice Guidelines in Oncology® Breast Cancer (Version 3.2017). © 2017 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed January 19, 2018.