

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

Treatment of germline *BRCA*-mutated advanced ovarian cancer: Monotherapy for patients with deleterious or suspected deleterious germline *BRCA* mutated (as detected by an FDA-approved test) advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy

The indication is approved under accelerated approval based on objective response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

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

II. CRITERIA FOR INITIAL APPROVAL

Authorization of 12 months may be granted for treatment of advanced ovarian cancer when all of the following criteria are met:

- A. Deleterious or suspected deleterious germline *BRCA* mutations
- B. Member has received treatment with three or more prior lines of chemotherapy

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 [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; January 2017.
2. National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology: ovarian cancer. Version 1.2016. http://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Accessed July 22, 2016.