Prior Authorization Approval Criteria

Lynparza (olaparib)

Generic name: Olaparib
Brand name: Lynparza
Medication class: Antitumor; polyadenosine 5-diphosphoribase polymerase (PARP) enzyme inhibitor
FDA-approved uses: Monotherapy in patients with deleterious or suspected deleterious germline BRCA mutated 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

Available dosage forms: 50mg capsules
Usual dose: 400mg orally twice daily
Approximate monthly cost: $13,440 (based on AWP)
Duration of therapy: Until disease progression or unacceptable toxicity

Criteria for use (bullet points below are all inclusive unless otherwise noted):
- The indicated diagnosis (including any applicable labs and/or tests) and medication usage must be supported by documentation from the patient’s medical records
- Clinically diagnosed with measurable deleterious or suspected deleterious germline BRCA mutated advanced ovarian cancer
- Trial and failure of at least three or more prior lines of chemotherapy
- ECOG PS of 0 or 1
- All prescriptions must be written for a 14 day supply

Criteria for continuation of therapy:
- Patient responding to treatment
- Patient tolerating treatment

Caution:
- Myelodysplastic Syndrome/Acute Myeloid Leukemia
- Pneumonitis
- Embryo-fetal toxicity
- Dose modifications for adverse reactions
- Dose modifications for use with CYP3A inhibitors

The criteria listed above applies to Fallon Health Plan and its subsidiaries.
Contraindication:
- None

Not approved if:
- Does not meet above criteria
- Has any contraindications to treatment

Special considerations:
- There were 8 (4%) patients with adverse reactions leading to death
- 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
- Lynparza was investigated in a single-arm study with a total of 137 patients. The partial response rate was 32% and the objective response rate was 34%.

Approval Duration:
- Initial 3 months
- Renewal 3 months

Fallon Health Pharmacy and Therapeutics Committee approval: ______________________

Date: 03/11/2015

Adopted: 3/11/15
Revised:
Effective: 5/11/15