Health and Community Services

OLAPARIB (LYNPARZA) 100MG AND 150MG TABLETS

Breast Cancer

1. For the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated high-risk early breast cancer who have had upfront surgery followed by adjuvant chemotherapy and who meet one of the following criteria:
   - Triple negative breast cancer and either axillary node-positive or axillary node-negative with invasive primary tumor pathological size of at least 2 cm (> pT2 cm).
   - Hormone receptor positive, HER2-negative breast cancer with at least 4 pathologically confirmed positive lymph nodes.

2. For the adjuvant treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated high-risk early breast cancer who received neoadjuvant chemotherapy followed by surgery and who meet one of the following criteria:
   - Triple negative breast cancer with residual invasive disease in the breast and/or resected lymph nodes (non-pCR).
   - Hormone receptor positive, HER2-negative breast cancer with residual invasive disease in the breast, and/or the resected lymph nodes, and a CPS + EG score of 3 or higher.

Clinical Notes:

1. Patients must have completed neoadjuvant or adjuvant chemotherapy containing an anthracycline and/or taxane.
2. Treatment should be initiated within 12 weeks of completion of the last treatment (i.e., surgery, chemotherapy, or radiation therapy).
3. Patients must have a good performance status.
4. Treatment should be discontinued upon disease recurrence, unacceptable toxicity, or completion of 1 year of therapy, whichever occurs first.

Claim Notes:

- Requests for patients determined to be at high-risk for relapse using a disease scoring system other than CPS + EG will be considered.
- Approval period: 1 year.

Metastatic Castration-Resistant Prostate Cancer

As monotherapy for the treatment of patients with metastatic castration-resistant prostate cancer (mCRPC) who meet all of the following criteria:

- Deleterious or suspected deleterious germline and/or somatic mutations in the homologous recombination repair (HRR) genes BRCA1, BRCA2 or ATM; and
- Disease progression on prior treatment with androgen-receptor-axis-targeted (ARAT) therapy.

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:

1. Patients must have a good performance status.
2. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:

- Approval period: 1 year.

Ovarian Cancer

1. As monotherapy maintenance treatment of patients with newly-diagnosed, advanced, BRCA-mutated (germline or somatic), epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
   - Complete or partial radiologic response after at least 4 cycles of first-line platinum-based chemotherapy
   - Last cycle of platinum-based chemotherapy was completed within the previous 12 weeks
   - High-grade serous or endometrioid tumors classified as Stage III or IV according to the International Federation of Gynecology and Obstetrics (FIGO) criteria

Renewal Criteria:

- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.
- Requests for treatment beyond 2 years will not be considered if there is no evidence of disease.

Clinical Notes:

1. Patients should have a good performance status and no active or uncontrolled metastases to the central nervous system.
2. Treatment should continue until unacceptable toxicity, disease progression, or to a maximum of 2 years of therapy if no evidence of disease, whichever comes first.[1]
3. Imaging is required for patients who are delayed in starting olaparib therapy, i.e. greater than 12 weeks after completion of platinum-based chemotherapy, or who have had a break in therapy for more than 14 days, to rule out progression prior to starting or re-starting olaparib.

[1]Patients with a partial response or stable disease at 2 years may continue to receive olaparib at the discretion of the treating physician.

Claim Notes:

- Requests for olaparib will not be considered for patients who experience disease progression on a PARP-inhibitor or who complete treatment with a PARP-inhibitor in a prior line of therapy
- Requests for olaparib in combination with bevacizumab will not be considered. Patients already on bevacizumab maintenance at the time of olaparib funding

may be switched to olaparib, as long as there is no evidence of progression on imaging and is within 12 weeks of completion of chemotherapy.
- Approval period: 1 year
- Renewal period: 1 year

2. As monotherapy maintenance treatment for patients with platinum-sensitive, recurrent, BRCA-mutated (germline or somatic) epithelial ovarian, fallopian tube, or primary peritoneal cancer who meet all of the following criteria:
   - Completed at least 2 previous lines of platinum-based chemotherapy
   - Received at least 4 cycles of the most recent platinum-based chemotherapy and in complete or partial radiologic response
   - Last cycle of platinum-based chemotherapy was completed within the previous 12 weeks
   - High-grade serous or endometrioid histology

Renewal Criteria:
- Written confirmation that the patient has responded to treatment and there is no evidence of disease progression.

Clinical Notes:
1. Platinum-sensitive disease is defined as disease progression occurring at least 6 months after completion of platinum-based chemotherapy.
2. Patients must have a good performance status and no active or uncontrolled metastases to the central nervous system.
3. Treatment should be discontinued upon disease progression or unacceptable toxicity.

Claim Notes:
- Requests for olaparib will not be considered for patients who experience disease progression on a PARP-inhibitor or who complete treatment with a PARP-inhibitor in a prior line of therapy
- Approval period: 1 year.

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