Lynparza® (olaparib) – New indication

- On January 12, 2018, the FDA announced the approval of AstraZeneca's Lynparza (olaparib) tablets, for patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm), human epidermal growth factor receptor 2 (HER2)-negative metastatic breast cancer, who have previously been treated with chemotherapy in the neoadjuvant, adjuvant or metastatic setting.
    - Patients with hormone receptor-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment.
    - Select patients for therapy based on an FDA-approved companion diagnostic, BRACAnalysis CDx®, for Lynparza.
- Lynparza is also approved for the treatment of ovarian cancer as follows:
    - 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.
    - For the treatment of adult patients with deleterious or suspected deleterious gBRCAm advanced ovarian cancer who have been treated with three or more prior lines of chemotherapy.
- Lynparza is also available as a 50 mg capsule approved for in patients with advanced gBRCAm ovarian cancer after three or more lines of chemotherapy.
- According to the National Cancer Institute, there were 252,710 new cases of breast cancer and 40,610 deaths from breast cancer in 2017 in the U.S.
    - Approximately 20 – 25% of patients with hereditary breast cancers and 5 – 10% of patients with any type of breast cancer have a BRCA mutation.
- Lynparza is the first poly ADP-ribose polymerase inhibitor approved to treat breast cancer. Lynparza is the first drug approved to treat certain patients with metastatic breast cancer who have a gBRCAm.
- The new indication of Lynparza was approved based on a randomized study of 302 patients with HER2-negative metastatic breast cancer with gBRCAm. Patients received Lynparza or chemotherapy. The major efficacy measure was progression free survival (PFS).
    - The median PFS for patients taking Lynparza was 7 months vs. 4.2 months for patients taking chemotherapy (HR = 0.58 [95% CI: 0.43, 0.80]; p = 0.0009).
    - The objective response rate was 52% (95% CI: 44, 60) for the Lynparza arm vs. 23% (95% CI: 13, 35) for the chemotherapy arm.
- The recommended dosage of Lynparza for all indications is 300 mg (two 150 mg tablets) taken orally twice daily, with or without food, for a total daily dose of 600 mg.

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- Lynparza tablets (100 mg and 150 mg) should not be substituted with Lynparza capsules (50 mg) on a milligram-to-milligram basis due to differences in the dosing and bioavailability of each formulation.