RATIONALE FOR INCLUSION IN PA PROGRAM

Background
Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. Lynparza is intended for women with heavily pretreated ovarian cancer that is associated with defective BRCA genes, or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. Ovarian cancer forms in the ovary, one of a pair of female reproductive glands where ova, or eggs, are formed. The BRCA genes are involved with repairing damaged DNA and normally work to suppress tumor growth. Women with mutations resulting in defective BRCA genes are more likely to get ovarian cancer. Additionally, Lynparza has gained FDA approval for the treatment of adults with metastatic breast cancer who have, or are suspected to have, deleterious germline BRCA-mutated breast cancer. It is approved for women with breast cancer after receiving chemotherapy treatment in the neoadjuvant (used to shrink the cancer before surgery), adjuvant (systemic chemotherapy), or metastatic setting (1).

Regulatory Status
FDA-approved indication: Lynparza is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated:

1. 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. For the treatment of adult patients with deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer who has been treated with three or more prior lines of chemotherapy
3. For the treatment of breast cancer in in patients with deleterious or suspected deleterious 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 (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine treatment

Lynparza is associated with the development of myelodysplastic syndrome, a condition where the bone marrow is unable to produce enough functioning blood cells; acute myeloid leukemia, a bone marrow cancer; and lung inflammation (1).
Safety and effectiveness of Lynparza in patients less than 18 years of age have not been established (1).

Summary
Lynparza is a poly ADP-ribose polymerase (PARP) inhibitor that blocks enzymes involved in repairing damaged DNA. Lynparza is intended for women with heavily pretreated ovarian cancer that is associated with defective BRCA genes, or recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer. Lynparza is indicated as monotherapy in patients with deleterious or suspected deleterious germline BRCA mutated (as detected by an FDA-approved test) advanced ovarian cancer that have been treated with three or more prior lines of chemotherapy. Additionally, Lynparza has gained FDA approval for the treatment of adults with metastatic breast cancer who have, or are suspected to have, deleterious germline BRCA-mutated breast cancer. Safety and effectiveness of Lynparza in patients less than 18 years of age have not been established (1).

Prior approval is required to ensure the safe, clinically appropriate and cost effective use of Lynparza while maintaining optimal therapeutic outcomes.

References