Zejula® (niraparib) – Indication update

- On December 8, 2022, the FDA approved an update to GSK's label for Zejula (niraparib), restricting the indication for maintenance treatment of patients with recurrent ovarian cancer to those with a germline BRCA mutation only. The revised indication is as follows:
    - Maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAmut) recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- This update follows a November 11 announcement that GSK, at the request of the FDA, would restrict the second-line maintenance indication for Zejula to only the patient population with deleterious or suspected deleterious gBRCAmut.
- Physicians should not initiate new treatment with Zejula for maintenance treatment of patients with non-gBRCAmut platinum sensitive recurrent high grade serous epithelial ovarian, fallopian tube, or primary peritoneal cancer in the second or later line setting.
- Physicians who are currently treating patients with Zejula for patients with non-gBRCAmut platinum sensitive recurrent ovarian cancer in the second or later line maintenance setting are asked to discuss this information with those patients for an individual benefit-risk assessment so that they can make an informed decision regarding their ongoing care.
- The first-line indication of Zejula remains unchanged for the maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who have a complete or partial response to platinum-based chemotherapy.