Zejula® (niraparib) – Updated indication

- On June 18, 2025, the FDA approved an update to the label for GSK's Zejula (niraparib), **to narrow the indication for maintenance treatment of adult patients with advanced ovarian cancer in the first line setting to those with homologous recombination deficiency (HRD)-positive tumors only**. The revised indication is as follows:
    - Maintenance treatment of adult patients with advanced epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to first-line platinum-based chemotherapy and whose cancer is associated with HRD-positive status defined by either: a deleterious or suspected deleterious BRCA mutation, and/or genomic instability.
- Zejula is also approved for the maintenance treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer who are in a complete or partial response to platinum-based chemotherapy.
- The recommended dose of Zejula is 200 mg to 300 mg orally once daily, based on weight and specific use for ovarian cancer. Treatment should be continued until disease progression or unacceptable toxicity.
    - Refer to the Zejula drug label for complete dosing and administration recommendations.