

Zejula® (niraparib) – Indication update

- On December 8, 2022, the <u>FDA approved</u> an update to <u>GSK's</u> label for <u>Zejula (niraparib)</u>, 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 <u>November 11 announcement</u> 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.



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