BlueCross BlueShield Federal Employee Program

ZEJULA
(niraparib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Zejula is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, used in the treatment of adult patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer. Epithelial ovarian, fallopian tube or primary peritoneal cancer is a cancer of the tissue covering the ovary or lining the fallopian tube or abdominal wall (peritoneum). In vitro studies have shown that niraparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, apoptosis, and cell death (1).

Regulatory Status

FDA-approved indications: Zejula is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated: (1)

- for the 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.
- 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. Select patients for therapy based on an FDA-approved companion diagnostic for Zejula.

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) and bone marrow suppression have occurred in patients treated with Zejula. Monitor patients for hematological toxicity weekly for the first month, monthly for the next 11 months and periodically thereafter (i.e. monitor complete blood count). Discontinue if MDS/AML or bone marrow suppression is confirmed or until disease progression or unacceptable toxicity (1).

Hypertension and cardiovascular effects have been reported in patients treated with Zejula. Blood pressure and heart rate should be monitored weekly for the first 2 months, then monthly for the first year, and periodically thereafter while on Zejula (1).

Posterior reversible encephalopathy syndrome (PRES) have occurred in patients treated with Zejula. Signs and symptoms of PRES include seizure, headache, altered mental status, visual disturbance, or cortical blindness, with or without associated hypertension. Patients treated with Zejula should be monitored for signs and symptoms of PRES and if suspected, Zejula should be

discontinued (1).

Zejula can cause fetal harm when administered to a pregnant woman. Advise females of reproductive potential to use effective contraception during treatment and for 6 months following the last dose of Zejula (1).

The safety and effectiveness of Zejula in pediatric patients have not been established (1).

Summary

Zejula is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, which (when uninhibited) play a role in DNA repair. Zejula is indicated for the treatment of patients with epithelial ovarian, fallopian tube, or primary peritoneal cancer. MDS/AML occurred in patients treated with Zejula, therefore monthly testing for hematological toxicity is required during treatment with Zejula. Hypertension and cardiovascular effects have been reported in patients treated with Zejula. Blood pressure and heart rate should be monitored weekly for the first 2 months, then monthly for the first year, and periodically throughout treatment. The safety and effectiveness of Zejula in pediatric patients have not been established (1).

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

References

1. Zejula [Package Insert]. Research Triangle Park, NC: GlaxoSmithKline; January 2024.
2. NCCN Drugs & Biologics Compendium ® Niraparib 2024. National Comprehensive Cancer Network, Inc. Accessed on October 3, 2024.