BlueCross BlueShield Federal Employee Program

TALZENNA (talazoparib)

RATIONALE FOR INCLUSION IN PA PROGRAM

Background

Talzenna (talazoparib) is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1 and PARP2 which play a role in DNA repair. Talazoparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, decreased cell proliferation, and apoptosis. Talazoparib anti-tumor activity was observed in human patient-derived xenograft breast cancer tumor models that expressed mutated or wild-type BRCA 1 and 2 (1).

Regulatory Status

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

1. As a single agent, for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer. Select patients based on an FDA-approved companion diagnostic for Talzenna.
2. In combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML) can occur in patients treated with Talzenna. Talzenna should not be started until patients have adequately recovered from hematological toxicity caused by previous chemotherapy. Complete blood counts should be monitored for cytopenia at baseline and monthly thereafter. If MDS/AML is confirmed, Talzenna should be discontinued (1).

Talzenna can also cause myelosuppression, consisting of anemia, leukopenia/neutropenia, and/or thrombocytopenia. Talzenna should not be started until patients have adequately recovered from hematological toxicity caused by previous chemotherapy (1).

Patients with moderate or severe renal impairment have a higher exposure to Talzenna than patients with normal renal function. Reduce the recommended dose of Talzenna in patients with moderate (CLcr 30 – 59 mL/min) and severe (CLcr 15 – 29 mL/min) renal impairment. Monitor

patients with severe renal impairment for potential increased adverse reactions and adjust dosing accordingly (1).

Talzenna can cause fetal harm when administered to a pregnant woman. Females of reproductive potential should be advised to use effective contraception during treatment and for at least 7 months following the last dose of Talzenna. Male patients with female partners of reproductive potential or who are pregnant should be advised to use effective contraception during treatment and for at least 4 months following the last dose of Talzenna (1).

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

Summary

Talzenna (talazoparib) is an inhibitor of poly (ADP-ribose) polymerase (PARP) enzymes, including PARP1 and PARP2 which play a role in DNA repair. Talazoparib-induced cytotoxicity may involve inhibition of PARP enzymatic activity and increased formation of PARP-DNA complexes resulting in DNA damage, decreased cell proliferation, and apoptosis. Talazoparib anti-tumor activity was observed in human patient-derived xenograft breast cancer tumor models that expressed mutated or wild-type BRCA 1 and 2. The safety and effectiveness of Talzenna in pediatric patients have not been established (1).

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

References

1. Talzenna [package insert]. New York, NY: Pfizer Inc.; February 2024.
2. NCCN Drugs & Biologics Compendium® Talazoparib 2025. National Comprehensive Cancer Network, Inc. Accessed on January 8, 2025.