ICD-10-CM Code Reference Guide

This ICD-10-CM Code Reference Guide provides a brief list of relevant coding information for TALZENNA® (talazoparib) when used in combination with enzalutimide. Use of these codes does not guarantee that the health plan will provide reimbursement for TALZENNA®, and is not intended to be a substitute for, or an influence on, providers' independent medical judgment.

ICD-10-CM Code[1]	Descriptor
C61	Malignant neoplasm of prostate
C77.1, C77.2, C77.4-C77.9, C78.7, C79.51	Secondary and unspecified malignant neoplasm of lymph nodes and other sites
R97.21	Rising PSA following treatment for malignant neoplasm of prostate
Z19.2	Hormone resistant malignancy status
Z85.46	Personal history of malignant neoplasm of prostate
Z92.21	Personal history of antineoplastic chemotherapy
Z92.29	Personal history of other drug therapy

Pfizer makes no guarantee regarding reimbursement for any service or item.

The information provided in this document is intended for informational purposes only and is not a comprehensive description of potential coding requirements for TALZENNA®. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and accurate and appropriate coding for treatment of his/her own patients. The information provided here should not be considered a guarantee of coverage or reimbursement for TALZENNA®.

ICD-10-CM=International Classification of Diseases, 10th edition, Clinical Modification; PSA=prostate-specific antigen.

Reference: 1. Centers for Medicare & Medicaid Services. 2023 ICD-10-CM Codes. Accessed February 23, 2023. https://www.cms.gov/medicare/icd-10/2023-icd-10-cm

INDICATION

TALZENNA is indicated in combination with enzalutamide for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).

Please see the Important Safety Information here. Click for the TALZENNA Full Prescribing Information.

TALZENNA®
talazoparib 0.5mg capsules

IMPORTANT SAFETY INFORMATION

WARNINGS and PRECAUTIONS

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), including cases with a fatal outcome, has been reported in patients who received TALZENNA. Overall, MDS/AML has been reported in 0.4% (3 out of 788) of solid tumor patients treated with TALZENNA as a single agent in clinical studies. In TALAPRO-2, MDS/AML occurred in 2 out of 511 (0.4%) patients treated with TALZENNA and enzalutamide and in 0 out of 517 (0%) patients treated with placebo and enzalutamide. The durations of TALZENNA treatment in these five patients prior to developing MDS/AML were 0.3, 1, 2, 3, and 5 years, respectively. Most of these patients had received previous chemotherapy with platinum agents and/or other DNA damaging agents including radiotherapy.

Do not start TALZENNA until patients have adequately recovered from hematological toxicity caused by previous chemotherapy. Monitor blood counts monthly during treatment with TALZENNA. For prolonged hematological toxicities, interrupt TALZENNA and monitor blood counts weekly until recovery. If counts do not recover within 4 weeks, refer the patient to a hematologist for further investigations including bone marrow analysis and blood sample for cytogenetics. If MDS/AML is confirmed, discontinue TALZENNA.

Myelosuppression consisting of anemia, neutropenia, and/or thrombocytopenia have been reported in patients treated with TALZENNA. In TALAPRO-2, Grade ≥3 anemia, neutropenia, and thrombocytopenia were reported, respectively, in 45%, 18%, and 8% of patients receiving TALZENNA and enzalutamide. Overall, 39% of patients (199/511) required a red blood cell transfusion, including 22% (111/511) who required multiple transfusions. Discontinuation due to anemia, neutropenia, and thrombocytopenia occurred, respectively, in 7%, 3%, and 0.4% of patients.

Withhold TALZENNA until patients have adequately recovered from hematological toxicity caused by previous therapy. Monitor blood counts monthly during treatment with TALZENNA. If hematological toxicities do not resolve within 28 days, discontinue TALZENNA and refer the patient to a hematologist for further investigations including bone marrow analysis and blood sample for cytogenetics.

Embryo-Fetal Toxicity TALZENNA can cause fetal harm when administered to pregnant women. Advise male patients with female partners of reproductive potential or who are pregnant to use effective contraception during treatment with TALZENNA and for 4 months after receiving the last dose.

ADVERSE REACTIONS

Serious adverse reactions reported in >2% of patients included anemia (9%) and fracture (3%). Fatal adverse reactions occurred in 1.5% of patients, including pneumonia, COVID infection, and sepsis (1 patient each).

The most common adverse reactions (≥ 10%, all Grades), including laboratory abnormalities, for patients in the TALAPRO-2 study who received TALZENNA in combination with enzalutamide vs patients receiving placebo with enzalutamide were hemoglobin decreased (79% vs 34%), neutrophils decreased (60% vs 18%), lymphocytes decreased (58% vs 36%), fatigue (49% vs 40%), platelets decreased (45% vs 8%), calcium decreased (25% vs 11%), nausea (21% vs 17%), decreased appetite (20% vs 14%), sodium decreased (22% vs 20%), phosphate decreased (17% vs 13%), fractures (14% vs 10%), magnesium decreased (14% vs 12%), dizziness (13% vs 9%), bilirubin increased (11% vs 7%), potassium decreased (11% vs 7%), and dysgeusia (10% vs 4.5%).

Clinically relevant adverse reactions in <10% of patients who received TALZENNA with enzalutamide included abdominal pain (9%), vomiting (9%), alopecia (7%), dyspepsia (4%), venous thromboembolism (3%) and stomatitis (2%).

Based on animal studies, TALZENNA may impair fertility in males of reproductive potential.

DRUG INTERACTIONS

Coadministration with P-gp inhibitors The effect of coadministration of P-gp inhibitors on talazoparib exposure when TALZENNA is taken in combination with enzalutamide has not been studied. Monitor patients for increased adverse reactions and modify the dosage as recommended for adverse reactions when TALZENNA is coadministered with a P-gp inhibitor.

Coadministration with BCRP inhibitors Monitor patients for increased adverse reactions and modify the dosage as recommended for adverse reactions when TALZENNA is coadministered with a BCRP inhibitor. Coadministration of TALZENNA with BCRP inhibitors may increase talazoparib exposure, which may increase the risk of adverse reactions.

USE IN SPECIFIC POPULATIONS

Renal Impairment The recommended dosage of TALZENNA for patients with moderate renal impairment (CLcr 30 - 59 mL/min) is 0.35 mg taken orally once daily in combination with enzalutamide. The recommended dosage of TALZENNA for patients with severe renal impairment (CLcr 15 - 29 mL/min) is 0.25 mg taken orally once daily in combination with enzalutamide. No dose adjustment is required for patients with mild renal impairment. TALZENNA has not been studied in patients requiring hemodialysis.