TALZENNA®
talazoparib 0.5mg capsules

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ACCESS AND REIMBURSEMENT GUIDE

Information to assist with gaining access and reimbursement for TALZENNA® (talazoparib)

Accurate completion of reimbursement-related or coverage-related documentation is the responsibility of the provider and patient. This information is general in nature and is not intended to be exhaustive. Pfizer makes no guarantee regarding reimbursement for any service or item.

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).

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.

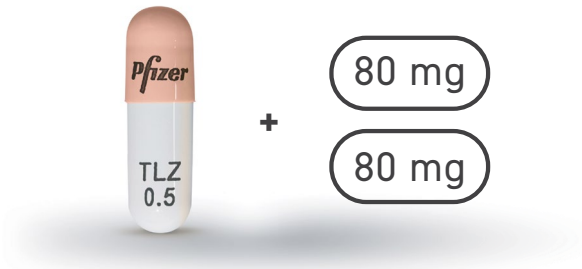
Do not start TALZENNA until patients have adequately recovered from hematological toxicity caused by previous chemotherapy. Monitor blood counts

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

TALZENNA® Indication, Dosing, and Administration

TALZENNA® is indicated in combination with enzalutamide for the treatment of adult patients with (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC).[1]

AS FEW AS 3 PILLS DAILY



One 0.5 mg capsule of TALZENNA®

160 mg enzalutamide daily

Not actual size.

TALZENNA® Recommended Once-Daily Starting Dose

Patients should also receive a gonadotropin-releasing hormone (GnRH) analog concurrently or should have had bilateral orchiectomy.[1]

Please refer to the enzalutamide Prescribing Information for recommended dosing information.

Myelodysplastic Syndrome/Acute Myeloid Leukemia (MDS/AML), continued

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,

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Coding

NDC and ICD-10-CM codes may be required to support the use of TALZENNA®. 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, your independent medical judgment.

National Drug Codes (NDC)[1]

DOSAGE	NDC
0.5 mg Capsules - 30 ct Bottle	0069-1501-30
0.35 mg Capsules - 30 ct Bottle	0069-1235-30
0.25 mg Capsules - 30 ct Bottle	0069-0296-30
0.1 mg Capsules - 30 ct Bottle	0069-1031-30

ICD-10-CM Codes[2]

ICD-10-CM CODE	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

Myelosuppression, continued

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

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Insurance Coverage

Although all payers leverage similar drug management tools such as prior authorization and step therapy, you will have to be aware of their unique nuances.

Prior Authorization/Medical Exception: If TALZENNA® is covered

Even if TALZENNA® is covered, payers may require prior authorization to determine appropriate use of therapy. The Prior Authorization Checklist and Sample Letter of Medical Necessity are resources available on Pfizer Oncology Together that might help your patient secure coverage for TALZENNA®.

Exception Request

If TALZENNA® is not on formulary, requires step therapy, or has quantity/dosage limits

If TALZENNA® is not on a payer's formulary, requires step therapy, or has quantity/dosage limits, you can request an exception. The **Sample Letter of Exception** is a resource available on Pfizer Oncology Together that might help with the exception request for TALZENNA®.

Appeal

If claim is denied

If your request for TALZENNA® coverage is denied by a payer, you can file an appeal in which you explain to the payer why you believe the decision was incorrect. The **Appeals Checklist** and **Sample Letter of Appeal** are resources available on Pfizer Oncology Together that might help to appeal a denied claim for TALZENNA®.

Visit **www.pfizeroncologytogether.com/hcp/products** and scroll down to TALZENNA® to download checklists and sample letters

ADVERSE REACTIONS, continued

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

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Specialty Pharmacies

TALZENNA® is available through specialty pharmacies listed below (other institutions and accounts may also be able to dispense TALZENNA®). Remember, specialty pharmacies may be able to verify insurance coverage, identify available patient assistance programs, and support adherence to therapy.

SPECIALTY PHARMACY	PHONE	FAX
AcariaHealth™ | acariahealth.envolvehealth.com	(866) 892-1580	(866) 892-2363
Accredo® Health Group, Inc. | accredo.com	(877) 732-3431	(888) 302-1028
AllianceRx Walgreens Pharmacy | alliancerxwp.com	(888) 347-3416	(877) 235-9807
Amber Specialty Pharmacy | amberpharmacy.com	(888) 370-1724	(877) 645-7514
Biologics by McKesson | biologicsinc.com	(800) 850-4306	(800) 823-4506
BioPlus® Specialty Pharmacy | bioplusrx.com	(888) 292-0744	(800) 269-5493
CenterWell Specialty Pharmacy | centerwellspecialtypharmacy.com	(800) 486-2668	(877) 405-7940
CVS Caremark Specialty™ Pharmacy | cvsspecialty.com	(855) 539-4712	(888) 435-1256
Elixir Pharmacy | envisionpharmacies.com	(877) 437-9012	(877) 309-0687
Kroger Specialty Pharmacy | krogerspecialtypharmacy.com	(888) 506-2962	(888) 315-3270
Onco360® Oncology Pharmacy | onco360.com	(877) 662-6633	(877) 662-6355
Optum Specialty Pharmacy | specialty.optumrx.com	(877) 455-6874	(877) 342-4596

Pfizer Oncology Together can identify which specialty pharmacies may be used based on the patient's network

Coadministration with P-gp inhibitors, continued

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.

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Helping patients get support. Together.

Pfizer Oncology together™

At Pfizer Oncology Together, patient support is at the core of everything we do.

FORMS & RESOURCES

Find forms to help patients access their prescribed Pfizer Oncology medications, including:

- Program enrollment
- Product access
- Sample letters and checklists
- Billing and coding information
- Co-pay assistance

FIND FORMS

CO-PAY ASSISTANCE

Eligible, commercially insured patients may pay as little as $0 per month for their oral medications or per treatment for certain injectable medications. Limits, terms, and conditions apply.*

CHECK ELIGIBILITY

PATIENT SUPPORT

Pfizer Oncology patients can be partnered with a dedicated Care Champion who has social work experience. Patients will receive practical help with day-to-day challenges, including filling out forms. They'll also have access to a library of downloadable patient resources.

GET PATIENT SUPPORT

* For oral products, click here, and for injectable products, click here. Patients are not eligible for these programs if they are enrolled in a state or federally funded insurance program, including but not limited to Medicare, Medicaid, TRICARE, Veterans Affairs health care, a state prescription drug assistance program, or the Government Health Insurance Plan available in Puerto Rico. For oral products, patients may receive up to $25,000 per product in savings annually. For injectable products, maximum annual patient savings range from $10,000 to $25,000. **For oral products, the offer will be accepted only at participating pharmacies. This offer is not health insurance.** No membership fees apply. Pfizer reserves the right to rescind, revoke, or amend this offer without notice. For any questions, please call 1-877-744-5675 or write: Pfizer Oncology Together Co-Pay Savings Program, 2250 Perimeter Park Drive, Suite 300, Morrisville, NC 27560.

FOR LIVE, PERSONALIZED SUPPORT
Call 1-877-744-5675 (Monday-Friday 8 AM-8 PM ET)

Visit PfizerOncologyTogether.com

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GnRH=gonadotropin-releasing hormone; HRR=homologous recombination repair; ICD-10-CM=International Classification of Diseases, 10th edition, Clinical Modification; mCRPC=metastatic castration-resistant prostate cancer; NDC=National Drug Code; PSA=prostate-specific antigen.

References: 1. TALZENNA® [Prescribing Information]. New York, NY: Pfizer Labs. **2.** 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