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Section:	Prescription Drugs	**Effective Date:**	April 1, 2026
Subsection:	Antineoplastic Agents	**Original Policy Date:**	November 2, 2018
Subject:	Talzenna	**Page:**	1 of 5

Last Review Date: March 6, 2026

Talzenna

Description

Talzenna (talazoparib)

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).

Related policies
Lynparza

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Talzenna may be considered **medically necessary** if the conditions indicated below are met.

Talzenna may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Locally advanced or metastatic breast cancer
    a. BRCA-positive mutation as detected by an FDA-approved test
    b. HER2-negative

2. Metastatic castration-resistant prostate cancer (mCRPC)
    a. Used in combination with Xtandi (enzalutamide)
    b. Homologous recombination repair (HRR) gene-mutation
    c. Patient has had a bilateral orchiectomy **OR** patient will be receiving a gonadotropin-releasing hormone (GnRH) analog concurrently

AND ALL of the following for **ALL** indications:

1. Prescriber agrees to monitor complete blood counts at baseline and monthly thereafter
2. Prescriber agrees to monitor renal function and adjust dosing accordingly
3. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for 7 months after the last dose
4. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for 4 months after the last dose

Prior – Approval *Renewal* Requirements

Age 18 years of age and older

Diagnoses

Patient must have **ONE** of the following:

1. Locally advanced or metastatic breast cancer
2. Metastatic castration-resistant prostate cancer (mCRPC)

AND ALL of the following for **ALL** indications:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor complete blood counts monthly
3. Prescriber agrees to monitor renal function and adjust dosing accordingly
4. Females of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for 7 months after the last dose

5. Males with female partners of reproductive potential **only**: patient will be advised to use effective contraception during therapy and for 4 months after the last dose

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Quantity 90 capsules per 90 days

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

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.; June 2025.
2. NCCN Drugs & Biologics Compendium® Talazoparib 2026. National Comprehensive Cancer Network, Inc. Accessed on January 12, 2026.

Policy History

Date	Action
November 2018	Annual review, Addition to PA
March 2019	Annual review
June 2020	Annual review and reference update
December 2021	Annual review and reference update
February 2022	Revised quantity chart to 90 capsules per 90 days. Also changed initiation duration from 6 to 12 months. Per FEP, added requirement “prescriber agrees to monitor renal function and adjust dosing accordingly”.
March 2022	Annual review and reference update
September 2022	Annual review and reference update
June 2023	Annual review and reference update
July 2023	Per PI update, added indication of HRR mutated mCRPC in combination with Xtandi
September 2023	Annual review and reference update
March 2024	Annual review and reference update
June 2024	Annual review and reference update
March 2025	Annual review and reference update
June 2025	Annual review and reference update
March 2026	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 6, 2026 and is effective on April 1, 2026.