

Applicable Drugs: Talzenna (talazoparib)

Preferred: N/A

Non-preferred: N/A

Date of Origin: 2/9/2026

Date Last Reviewed / Revised: N/A

PRIOR AUTHORIZATION CRITERIA

(May be considered medically necessary when criteria I to V are met.)

- I. Documentation of one of the following diagnoses A or B AND must meet all criteria listed under the applicable diagnosis:
FDA-Approved Indication(s)
 - A. Breast Cancer
 - i. Documentation of HER2-negative, locally advanced or metastatic disease.
 - ii. Documentation of a deleterious or suspected deleterious germline BRCA mutation (gBRCAm).
 - iii. Talzenna will be used as a single agent.
 - B. Prostate Cancer
 - i. Documentation of metastatic castration-resistant prostate cancer (mCRPC)
 - ii. Documentation of homologous recombination repair (HRR) gene-mutated disease (ATM, ATR, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C). Note: BRCA1 and BRCA2 mutations excluded.
 - iii. Talzenna will be used in combination with Xtandi (enzalutamide)
 - iv. Patient meets ONE of the following (1 or 2):
 1. Talzenna will be used in concurrently with a gonadotropin-releasing hormone (GnRH) analog (ex: leuprolide acetate, Lupron Depot [leuprolide acetate intramuscular injection], Eligard [leuprolide acetate injectable suspension], Firmagon (degarelix acetate subcutaneous injection, etc.), OR
 2. Patient has had a bilateral orchiectomy
- II. Minimum age requirement: 18 years old
- III. Treatment must be prescribed by or in consultation with an oncologist or hematologist.
- IV. Request is for a medication with the appropriate FDA labeling, or its use is supported by current National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1 or 2A.

- V. Refer to the plan document for the list of preferred products. If the requested agent is not listed as a preferred product, must have documented treatment failure or contraindication to the preferred product(s).

EXCLUSION CRITERIA

- BRCA1 and BRCA2 mutations for metastatic castration resistant prostate cancer.

OTHER CRITERIA

- N/A

QUANTITY / DAYS SUPPLY RESTRICTIONS

- Quantities limited to 30 (thirty) capsules per 30 days
 - Breast Cancer
 - Maximum dose: 1 mg once daily
 - Prostate Cancer
 - Maximum dose: 0.5 mg once daily

APPROVAL LENGTH

- **Authorization:** 12 months
- **Re-Authorization:** An updated letter of medical necessity or progress notes showing current medical necessity criteria are met and does not show evidence of progressive disease.

APPENDIX

N/A

REFERENCES

1. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Prostate Cancer. Version 4.2026. Updated December 4, 2025. Accessed December 14, 2025. www.nccn.org/professionals/physician_gls/pdf/prostate.pdf
2. National Comprehensive Cancer Network. Clinical Practice Guidelines in Oncology. Breast Cancer. Version 5.2025. Updated October 16, 2025. Accessed December 14, 2025.
3. Talzena. Prescribing Information. Pfizer Inc. 2025. Accessed November 14, 2025. www.labeling.pfizer.com/ShowLabeling.aspx?id=20582

DISCLAIMER: Medication Policies are developed to help ensure safe, effective and appropriate use of selected medications. They offer a guide to coverage and are not intended to dictate to providers how to practice medicine. Refer to Plan for individual adoption of specific Medication Policies. Providers are expected to exercise their medical judgement in providing the most appropriate care for their patients.