Reference number(s)
2782-A

Specialty Guideline Management
Talzenna

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Talzenna	talazoparib

Indications

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

FDA-Approved Indications[1]

Breast Cancer

Talzenna is indicated as a single agent for the treatment of adult patients with deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.

Prostate Cancer

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).

Compendial Uses[2]

- Human epidermal growth factor receptor 2 (HER2)-negative, BRCA 1/2-germline mutated breast cancer
- HER2-positive BRCA 1/2-germline mutated breast cancer
- Homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer

All other indications are considered experimental/investigational and not medically necessary.

Documentation

Submission of the following information is necessary to initiate the prior authorization review: BRCA mutation or HRR gene testing results.

Coverage Criteria

Breast Cancer[1,2]

Authorization of 12 months may be granted for treatment of breast cancer with no response to preoperative systemic therapy, or for locally advanced, recurrent, or metastatic breast cancer as a single agent in members with deleterious or suspected deleterious germline BRCA mutations.

Metastatic Castration-Resistant Prostate Cancer[1,2]

Authorization of 12 months may be granted for treatment of metastatic castration-resistant prostate cancer when all of the following criteria are met:

- The member has homologous recombination repair (HRR)-gene mutation which includes ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C.
- The member has not had treatment in the setting of castration-resistant prostate cancer.
- The requested medication will be used in combination with enzalutatmide (Xtandi).
- The member has had a bilateral orchiectomy or will be using the requested medication in combination with a luteinizing hormone-releasing hormone (LHRH) agonist (e.g., goserelin, leuprolide) or antagonist (e.g., degarelix, relugolix).
- Member has not progressed on prior novel hormone therapy (e.g., abiraterone, enzalutamide, darolutamide, or apalutamide).

Continuation of Therapy

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication in the Coverage Criteria section, specific to diagnosis, when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

References

1. Talzenna [package insert]. New York, NY: Pfizer Inc.; June 2025.
2. The NCCN Drugs & Biologics Compendium 2025 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed August 13, 2025.