

Talzenna (talazoparib)

Override(s)	Approval Duration
Prior Authorization Quantity Limit	1 year

Medications	Quantity Limit
Talzenna (talazoparib)	May be subject to quantity limit

APPROVAL CRITERIA

Requests for Talzenna (talazoparib) may be approved if the following criteria are met:

- I. Individual has a diagnosis of recurrent unresectable or metastatic breast cancer (Label, NCCN 1, 2A); **AND**
- II. Individual has results confirmed for deleterious or suspected deleterious germline BRCA-mutation (gBRCAm) and human epidermal growth factor receptor 2 (HER2) breast cancer; **AND**
- III. Individual is using as a single agent;

OR

- IV. Individual has a diagnosis of recurrent unresectable or metastatic triple-negative breast cancer (TNBC) (NCCN 1); **AND**
- V. Individual has BRCA 1/2 germline mutated disease;

OR

- VI. Individual has a diagnosis of metastatic castration-resistant prostate cancer (mCRPC) (Label, NCCN 1, 2A); **AND**
- VII. Individual has homologous recombination repair (HRR) mutation including ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C; **AND**
- VIII. Using in combination with enzalutamide (Xtandi); **AND**
- IX. One of the following:
 - A. Individual is concomitantly receiving a gonadotropin-releasing hormone (GnRH) analog (e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix); **OR**
 - B. Has had a bilateral orchiectomy.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2024. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: March 1, 2024
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2024; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2024 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on March 1, 2024.
 - a. Breast Cancer. V1.2024. Revised January 25, 2024.
 - b. Prostate Cancer. V1.2024. Revised February 27, 2024.

Federal and state laws or requirements, contract language, and Plan utilization management programs or policies may take precedence over the application of this clinical criteria.

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