PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Talzenna Prior Authorization Policy
- Talzenna® (talazoparib capsules and liquid-filled soft gelatin capsules – Pfizer)

REVIEW DATE: 12/13/2023; selected revision 05/15/2024

OVERVIEW

Talzenna, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated for the following uses:[1]

- **Breast cancer**, for the treatment of deleterious or suspected deleterious germline BReast CAncer susceptibility gene (BRCA)-mutated human epidermal growth factor receptor 2 (HER2)-negative locally-advanced or metastatic breast cancer in adults.
- **Prostate cancer**, for the treatment of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) in combination with Xtandi® (enzalutamide capsules or tablets) in adults.

GUIDELINES

Talzenna is discussed in guidelines from the National Comprehensive Cancer Network (NCCN):

- **Breast Cancer**: NCCN guidelines (version 5.2023 – December 5, 2023) recommend Talzenna for patients with recurrent unresectable (local or regional) or Stage IV disease breast cancer with hormone receptor-positive, HER2-negative disease with visceral crisis or endocrine-refractory, germline *BRCA1/2* mutation as a "Preferred Regimen" (category 1).[2] Lynparza® (olaparib tablets) is another "Preferred Regimen" in this setting (category 1). There is a footnote which states PARP inhibitors can be considered for a later line for those with *BRCA*1/2 mutation, however, available evidence suggests it is more effective if used earlier. Talzenna is also recommended as a single-agent for recurrent, unresectable, or stage IV HER2-positive disease with a *BRCA1/2* mutation (category 2A). The guidelines note that although Talzenna and Lynparza are FDA-approved for HER2-negative disease, the NCCN Panel supports use of these agents in any subtype associated with a germline *BRCA1/2* mutation. For triple negative breast cancer with germline *BRCA*1/2 mutation, Talzenna and Lynparza are listed as a "Preferred Regimens" in the first-line setting for patients with programmed cell death ligand 1 combined positive score (PD-L1 CPS) < 10 (category 1), and also in the second-line setting (category 1).
- **Prostate Cancer:** NCCN guidelines (version 4.2023 – September 7, 2023) recommend Talzenna + Xtandi for HRR mutation (category 1) as "Useful in Certain Circumstances" in the first-line setting for mCRPC. For patients who have received prior novel hormone therapy and no prior docetaxel therapy, Talzenna + Xtandi is recommended for HRR mutation (category 2B) as "Useful in Certain Circumstances". For patients who have received prior docetaxel therapy and no prior novel hormone therapy, Talzenna + Xtandi is recommended for HRR mutation (category 2A) as "Useful in Certain Circumstances".

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Talzenna. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Talzenna is recommended in those who meet one of the following criteria:

FDA-Approved Indication

1. **Breast Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has recurrent or metastatic breast cancer; AND
   - **C)** Patients has germline *BRCA* mutation-positive disease.

2. **Prostate Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, C, D, and E):
   - **A)** Patient is ≥ 18 years of age; AND
   - **B)** Patient has metastatic castration resistant prostate cancer; AND
   - **C)** Patient meets ONE of the following criteria (i or ii):
     - **i.** The medication is used concurrently with a gonadotropin-releasing hormone (GnRH) analog; OR
       Note: Examples are leuprolide acetate, Lupron Depot (leuprolide acetate intramuscular injection), Trelstar (triptorelin pamoate intramuscular injection), Zoladex (goserelin acetate subcutaneous implant), Vantas (histrelin acetate subcutaneous implant), Firmagon (degarelix acetate subcutaneous injection), Orgovyx (relugolix tablets).
     - **ii.** Patient has had a bilateral orchiectomy; AND
   - **D)** Patient has homologous recombination repair (HRR) gene-mutated disease; AND
     Note: HRR gene mutations include *ATM, ATR, BRCA1, BRCA2, CDK12, CHEK2, FANCA, MLH1, MRE11A, NBN, PALB2, or RAD51C*
   - **E)** The medication is used in combination with Xtandi (enzalutamide capsules and tablets).

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Talzenna is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Talzenna® capsules [prescribing information]. New York, NY: Pfizer; March 2024.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 5.2023 – December 5, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 12, 2023.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – September 7, 2023). © 2023National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 1, 2023.