VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Talzenna Prior Authorization Policy
- Talzenna® (talazoparib capsules – Pfizer)

REVIEW DATE: 11/30/2022; selected revision 03/01/2023 and 06/28/2023

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 4.2023 – March 23, 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 (category 1), and also in the second-line setting for patients with programmed cell death ligand 1 combined positive score (PD-L1 CPS) < 10 (category 1).
- **Prostate Cancer:** NCCN guidelines (version 1.2023 – September 16, 2022) do not address Talzenna. NCCN guidelines recommend Lynparza as "Useful in Certain Circumstances" for mCRPC with germline or somatic HRR mutation for patients who have received prior novel hormone therapy (i.e. abiraterone, Xtandi, Nubeqa® [darolutamide tablets], or Erleada® [apalutamide tablets]) [category 1; category 2B if the patient has visceral metastases and has tried docetaxel].[3] Rubraca® (rucaparib tablets) is also recommended in this setting if the patient has a *BRCA* mutation and if patient has been treated with androgen receptor-directed therapy and a taxane-based chemotherapy (category 2A; category 2B if visceral metastasis are present and patient has tried docetaxel).

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 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 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; June 2023.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2023 – March 23, 2023). © 2023 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on June 23, 2023.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2023 – September 16, 2022). © 2022 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed June 23, 2023.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	**Breast Cancer:** A requirement was added that the patient is ≥ 18 years of age.	11/17/2021
Selected Revision	**Breast Cancer:** The requirement that the patient has "locally advanced or metastatic disease" was changed to "recurrent or metastatic disease."	02/02/2022
Selected Revision	**Breast Cancer:** The duration of approval was changed from 3 years to 1 year.	06/22/2022
Annual Revision	No criteria changes.	11/30/2022
Selected Revision	**Breast Cancer:** The requirement that the patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer was removed.	03/01/2023
Selected Revision	**Prostate Cancer:** Condition of approval and criteria were added based on new FDA approved indication of treatment of homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC) in combination with Xtandi® (enzalutamide capsules or tablets) in adults.	06/28/2023