PRIOR AUTHORIZATION POLICY

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

REVIEW DATE: 01/08/2025

INSTRUCTIONS FOR USE

THE FOLLOWING COVERAGE POLICY APPLIES TO HEALTH BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. CERTAIN CIGNA COMPANIES AND/OR LINES OF BUSINESS ONLY PROVIDE UTILIZATION REVIEW SERVICES TO CLIENTS AND DO NOT MAKE COVERAGE DETERMINATIONS. REFERENCES TO STANDARD BENEFIT PLAN LANGUAGE AND COVERAGE DETERMINATIONS DO NOT APPLY TO THOSE CLIENTS. COVERAGE POLICIES ARE INTENDED TO PROVIDE GUIDANCE IN INTERPRETING CERTAIN STANDARD BENEFIT PLANS ADMINISTERED BY CIGNA COMPANIES. PLEASE NOTE, THE TERMS OF A CUSTOMER'S PARTICULAR BENEFIT PLAN DOCUMENT [GROUP SERVICE AGREEMENT, EVIDENCE OF COVERAGE, CERTIFICATE OF COVERAGE, SUMMARY PLAN DESCRIPTION (SPD) OR SIMILAR PLAN DOCUMENT] MAY DIFFER SIGNIFICANTLY FROM THE STANDARD BENEFIT PLANS UPON WHICH THESE COVERAGE POLICIES ARE BASED. FOR EXAMPLE, A CUSTOMER'S BENEFIT PLAN DOCUMENT MAY CONTAIN A SPECIFIC EXCLUSION RELATED TO A TOPIC ADDRESSED IN A COVERAGE POLICY. IN THE EVENT OF A CONFLICT, A CUSTOMER'S BENEFIT PLAN DOCUMENT ALWAYS SUPERSEDES THE INFORMATION IN THE COVERAGE POLICIES. IN THE ABSENCE OF A CONTROLLING FEDERAL OR STATE COVERAGE MANDATE, BENEFITS ARE ULTIMATELY DETERMINED BY THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT. COVERAGE DETERMINATIONS IN EACH SPECIFIC INSTANCE REQUIRE CONSIDERATION OF 1) THE TERMS OF THE APPLICABLE BENEFIT PLAN DOCUMENT IN EFFECT ON THE DATE OF SERVICE; 2) ANY APPLICABLE LAWS/REGULATIONS; 3) ANY RELEVANT COLLATERAL SOURCE MATERIALS INCLUDING COVERAGE POLICIES AND; 4) THE SPECIFIC FACTS OF THE PARTICULAR SITUATION. EACH COVERAGE REQUEST SHOULD BE REVIEWED ON ITS OWN MERITS. MEDICAL DIRECTORS ARE EXPECTED TO EXERCISE CLINICAL JUDGMENT AND HAVE DISCRETION IN MAKING INDIVIDUAL COVERAGE DETERMINATIONS. COVERAGE POLICIES RELATE EXCLUSIVELY TO THE ADMINISTRATION OF HEALTH BENEFIT PLANS. COVERAGE POLICIES ARE NOT RECOMMENDATIONS FOR TREATMENT AND SHOULD NEVER BE USED AS TREATMENT GUIDELINES. IN CERTAIN MARKETS, DELEGATED VENDOR GUIDELINES MAY BE USED TO SUPPORT MEDICAL NECESSITY AND OTHER COVERAGE DETERMINATIONS.

CIGNA NATIONAL FORMULARY COVERAGE:

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 as a single agent.
- **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 6.2024 – November 11, 2024) 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 as fourth-line therapy and beyond (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 1.2025 – December 4, 2024) recommend Talzenna + Xtandi for HRR mutation (category 1) as "Useful in Certain Circumstances" in the first-line setting for mCRPC. For patients who have progressed on 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 progressed on 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.

- **Talzenna® (talazoparib capsules and liquid-filled soft gelatin capsules – Pfizer)**

is(are) covered as medically necessary when the following criteria is(are) met for FDA-approved indication(s) or other uses with supportive evidence (if applicable):

FDA-Approved Indications

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 (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 COVERED

- **Talzenna® (talazoparib capsules and liquid-filled soft gelatin capsules – Pfizer)**

is(are) considered experimental, investigational or unproven for ANY other use(s); 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 6.2024 – November 11, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on December 31, 2024.
3. The NCCN Prostate Cancer Clinical Practice Guidelines in Oncology (version 1.2025 – December 4, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed December 31, 2024.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual Revision	No criteria changes.	12/13/2023
Selected Revision	A new formulation (Talzenna and liquid-filled soft gelatin capsules) was added to the policy. The same criteria apply as those for the Talzenna (talazoparib capsules).	05/15/2024
Annual Revision	No criteria changes.	01/08/2025