Talzenna® (talazoparib)
(Oral)

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I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

II. Dosing Limits

A. Quantity Limit (max daily dose) [NDC Unit]:

- Talzenna 0.1 mg capsule: 1 capsule per day
- Talzenna 0.25 mg capsule: 1 capsule per day
- Talzenna 0.35 mg capsule: 1 capsule per day
- Talzenna 0.5 mg capsule: 1 capsule per day
- Talzenna 0.75 mg capsule: 1 capsule per day
- Talzenna 1 mg capsule: 1 capsule per day

B. Max Units (per dose and over time) [HCPCS Unit]:

- Breast Cancer: 1 mg per day
- Prostate Cancer: 0.5 mg per day

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age; **AND**

Universal Criteria [1,2]

- Patient has not received previous treatment with a PARP-inhibitor (e.g., niraparib, rucaparib, olaparib, etc.) prior to initiating therapy; **AND**
- Patient will avoid concomitant use with P-gp inhibitors (e.g., itraconazole, amiodarone, carvedilol, clarithromycin, verapamil, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **AND**

Breast Cancer † ‡ [1-3,5]

- Used as single agent therapy; **AND**
- Patient has germline BRCA 1/2-mutated disease as detected by a CLIA-compliant or FDA-approved test❖; **AND**
    - Patient has HER2-negative disease; **AND**
        - Patient has locally advanced, recurrent unresectable, or metastatic disease OR inflammatory disease that has not responded to preoperative systemic therapy; **AND**
            - Patient has hormone receptor-negative disease Ψ; **OR**
            - Patient has hormone receptor-positive disease with visceral crisis or is endocrine therapy refractory; **OR**
    - Patient has HER2-positive disease; **AND**
        - Patient has recurrent unresectable or metastatic disease OR inflammatory disease that has not responded to preoperative systemic therapy

Prostate Cancer † [1]

- Used in combination with enzalutamide; **AND**
- Patient has metastatic castration-resistant prostate cancer (mCRPC); **AND**
- Patient has homologous recombination repair (HRR) gene-mutated disease as detected by a CLIA-compliant or FDA-approved test❖; **AND**
- Patient will receive concurrent treatment with a gonadotropin-releasing hormone (GnRH) analog (e.g., leuprolide, goserelin, triptorelin, histrelin, degarelix, etc.) OR has had a bilateral orchiectomy

❖ *If confirmed using an FDA-approved assay – http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

Ψ ER Scoring Interpretation *(following ER testing by validated IHC assay)*	
Results	**Interpretation**
– 0% – <1% of nuclei stain	– ER-negative
– 1%–10% of nuclei stain	– ER-low–positive*
– >10% of nuclei stain	– ER-positive
**Note: Patients with cancers with ER-low–positive (1%–10%) results are a heterogeneous group with reported biologic behavior often similar to ER-negative cancers; thus, as such these cancers inherently behave aggressively and may be treated similar to triple-negative disease. Individualized consideration of risks versus benefits should be incorporated into decision-making.*	

IV. Renewal Criteria [1]

Coverage may be renewed based on the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: myelodysplastic syndrome/acute myeloid leukemia (MDS/AML), myelosuppression (e.g., anemia, neutropenia, and/or thrombocytopenia), etc.

V. Dosage/Administration [1]

Indication	Dose
Breast Cancer	1 mg orally once daily until disease progression or unacceptable toxicity
Prostate Cancer	0.5 mg orally once daily until disease progression or unacceptable toxicity

VI. Billing Code/Availability Information

HCPCS Code(s):

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals (Hospital-Outpatient Prospective Payer System Use Only-HOPPS)

NDC(s):

- Talzenna 0.1 mg capsule: 00069-1031-xx
- Talzenna 0.25 mg capsule: 00069-0296-xx
- Talzenna 0.35 mg capsule: 00069-1235-xx
- Talzenna 0.5 mg capsule: 00069-1501-xx
- Talzenna 0.75 mg capsule: 00069-1751-xx
- Talzenna 1 mg capsule: 00069-1195-xx

VII. References

1. Talzenna [package insert]. New York, NY; Pfizer Labs; June 2023. Accessed January 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Talazoparib. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2024.

3. Litton JK, Rugo HS, Ettl J, et al. Talazoparib in Patients with Advanced Breast Cancer and a Germline BRCA Mutation. N Engl J Med. 2018 Aug 23;379(8):753-763. doi: 10.1056/NEJMoa1802905. Epub 2018 Aug 15.
4. Agarwal N, Azad A, Carles J, et al. TALAPRO-2: Phase 3 study of talazoparib (TALA) + enzalutamide (ENZA) versus placebo (PBO) + ENZA as first-line (1L) treatment in patients (pts) with metastatic castration-resistant prostate cancer (mCRPC). Journal of Clinical Oncology 2023 41:6_suppl, LBA17-LBA17. DOI: 10.1200/JCO.2023.41.6_suppl.LBA17.
5. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Breast Cancer. Version 5.2023. National Comprehensive Cancer Network, 2024. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed January 2024.

Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast

ICD-10	ICD-10 Description
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of right male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast

ICD-10	ICD-10 Description
C61	Malignant neoplasm of prostate

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp (WPS)
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA, LLC
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA, LLC
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC