UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2023 P 1266-6
Program	Prior Authorization/Notification
Medication	Talzenna® (talazoparib)
P&T Approval Date	12/2018, 12/2019, 12/2020, 12/2021, 12/2022, 8/2023
Effective Date	11/1/2023

1. Background:

Talzenna (talazoparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated as a single agent for the treatment of adult patients with deleterious or suspected deleterious germline BRCA mutated (*gBRCAm*), human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer. Appropriate patients for therapy are selected based on an FDA-approved companion diagnostic for Talzenna.[1] Talzenna is also indicated in combination with Xtandi (enzalutamide) for the treatment of adult patients with homologous recombination repair (HRR) gene-mutated metastatic castration-resistant prostate cancer (mCRPC). The National Comprehensive Cancer Network (NCCN) also supports use of Talzenna in any localized or metastatic breast cancer subtype associated with a germline BRCA1 or BRCA2 mutation.

Coverage Information:
Members will be required to meet the criteria below for coverage. For members under the age of 19 years, the prescription will automatically process without a coverage review.

Some states mandate benefit coverage for off-label use of medications for some diagnoses or under some circumstances. Some states also mandate usage of other Compendium references. Where such mandates apply, they supersede language in the benefit document or in the notification criteria.

2. Coverage Criteria[a]:

A. <u>Patients less than 19 years of age</u>

1. **Talzenna** will be approved based on the following criterion:

   a. Patient is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Breast Cancer</u>

1. **<u>Initial Authorization</u>**

   a. **Talzenna** will be approved based on **<u>all</u>** of the following criteria:

      (1) Diagnosis of breast cancer

      -AND-

      (2) Disease is **one** of the following:

(a) Locally advanced
(b) Metastatic

-AND-

(3) Presence of a germline BRCA-mutation

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Talzenna** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Talzenna therapy

Authorization will be issued for 12 months.

C. Prostate Cancer

1. **Initial Authorization**

a. **Talzenna** will be approved based on **all** of the following criteria:

(1) Diagnosis of metastatic castration-resistant prostate cancer

-AND-

(2) Presence of homologous recombination repair (HRR) gene mutations

-AND-

(3) Used in combination with Xtandi (enzalutamide)

-AND-

(4) **One** of the following:

(a) Used in combination with a gonadotropin-releasing hormone (GnRH) analog [e.g., Lupron (leuprolide), Zoladex (goserelin), Trelstar (triptorelin), Vantas (histrelin), Firmagon (degarelix)]

-OR-

(b) Patient has had bilateral orchiectomy

Authorization will be issued for 12 months.

2. **Reauthorization**

a. **Talzenna** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on Talzenna therapy

Authorization will be issued for 12 months.

D. NCCN Recommended Regimens

The drug has been recognized for treatment of the cancer indication by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium with a Category of Evidence and Consensus of 1, 2A, or 2B

Authorization will be issued for 12 months.

[a] State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class
- Supply limits may be in place.
- Step therapy may be in place.

4. References:

1. Talzenna [package insert]. New York, NY: Pfizer Labs, June 2023.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed July 16, 2023.

Program	Prior Authorization/Notification – Talzenna (talazoparib)
Change Control	
12/2018	New program.
12/2019	Annual review. Added general NCCN recommendations for use criteria. Updated background and references.
12/2020	Annual review. Added reference to step therapy policy. Updated references.
12/2021	Annual review. Updated clinical criteria based on NCCN recommendations. Updated references.
12/2022	Annual review. Added stated mandate and updated references.
8/2023	Added criteria for HRR gene-mutated mCRPC per label. Updated background and references.