UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2024 P 3122-6
Program	Step Therapy
Medication	Talzenna™ (talazoparib)
P&T Approval Date	4/2019, 4/2020, 4/2021, 4/2022, 4/2023, 4/2024
Effective Date	7/1/2024

1. Background:

Step therapy programs are utilized to encourage use of lower cost alternatives for certain therapeutic classes. This program requires a member to try Lynparza® (olaparib) before providing coverage for Talzenna for the treatment of germline *BRCA*-mutated (*gBRCAm*) human epidermal growth factor receptor 2 (HER2)-negative breast cancer.

Talzenna is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated for the treatment of adult patients with deleterious or suspected deleterious *gBRCAm,* HER2-negative locally advanced or metastatic breast cancer.

Lynparza is a PARP inhibitor indicated for the treatment of adult patients with deleterious or suspected deleterious *gBRCAm*, HER2-negative metastatic breast cancer who have been treated with chemotherapy in the neoadjuvant, adjuvant, or metastatic setting. Patients with hormone receptor (HR)-positive breast cancer should have been treated with a prior endocrine therapy or be considered inappropriate for endocrine therapy.

The National Comprehensive Cancer Network (NCCN) also supports use of Lynparza and Talzenna for treatment of *gBRCAm,* HER2-negative locally advanced or metastatic breast cancer.

Members currently on Talzenna therapy as documented in claims history will be allowed to continue on their current therapy. Members new to therapy will be required to meet the coverage criteria below.

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.

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2. Coverage Criteria [a,b]:

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

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

   a. Member is less than 19 years of age

   Authorization will be issued for 12 months.

B. <u>Breast Cancer</u>

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

   a. **<u>One</u>** of the following:

      (1) Patient has a contraindication or history of intolerance to Lynparza

      -OR-

      (2) Provider attests that the patient is not an appropriate candidate for Lynparza

      -OR-

      (3) **<u>Both</u>** of the following:

         (a) As continuation of therapy

         -AND-

         (b) Patient has **<u>not</u>** received a manufacturer supplied sample at no cost from a prescriber's office, or any form of assistance from the Pfizer Oncology Together sponsored Co-Pay Savings Program (e.g., sample card which can be redeemed at a pharmacy for a free supply of medication) or a 30 day free trial from a pharmacy as a means to establish as a current user of Talzenna

   *Patients requesting initial authorization who were established on therapy via the receipt of a manufacturer supplied sample at no cost in the prescriber's office or any form of assistance from the Pfizer Oncology Together sponsored Co-Pay Savings Program **<u>shall be required</u>** to meet initial authorization criteria as if patient were new to therapy.

   Authorization will be issued for 12 months.

C. <u>Other Indications</u>

1. **Talzenna** will be approved.

   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.
[b] Coverage of oncology medications may be approved based on state mandates.

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 and/or Notification may be in place.
- Coverage of oncology medications may be approved based on state mandates.

4. References:

1. Lynparza [package insert]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; November 2023.
2. Talzenna [package insert]. New York, NY: Pfizer Inc.; June 2023.
3. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed February 26, 2024.

Program	Step Therapy - Talzenna (talazoparib)
Change Control	
4/2019	New program.
4/2020	Annual review. Updated background and references.
4/2021	Annual review. No changes to clinical criteria. Updated references.
4/2022	Annual review. No changes to clinical criteria. Updated references. Updated oncology medications state mandate note.
4/2023	Annual review with no change to clinical coverage criteria. Updated background and references.
4/2024	Annual review with no change to coverage criteria. Updated references.