UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Talzenna

Program	Prior Authorization
Medication	Talzenna™ (talazoparib)
Markets in Scope	Arizona, California, Colorado, Hawaii, Maryland, Nevada, New Jersey, New York, New York EPP, Pennsylvania CHIP, Rhode Island, South Carolina
Issue Date	12/2018
Pharmacy and Therapeutics Approval Date	12/2020
Effective Date	1/2021

1. Background:

Talzenna (talazoparib) is a poly (ADP-ribose) polymerase (PARP) inhibitor indicated 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]

2. Coverage Criteria:

A. <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 **<u>one</u>** of the following:

(a) Locally advanced
(b) Metastatic
(

-AND-

(3) Presence of deleterious or suspected deleterious germline BRCA-mutations as detected by the FDA-approved companion diagnostic for Talzenna

-AND-

(4) Disease is human epidermal growth factor receptor 2 (HER2)-negative

-AND-

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

(a) Patient has a contraindication or history of intolerance to Lynparza
(b) Provider attests that the patient is not an appropriate candidate for Lynparza
(c) Patient is currently on Talzenna therapy

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.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Talzenna** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

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

(1) Documentation of positive clinical response to Talzenna therapy

Authorization will be issued for 12 months.

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.

4. References:

1. Talzenna [package insert]. New York, NY: Pfizer Labs; March 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at http://www.nccn.org/professionals/drug_compendium/content/contents.asp. Accessed October 26, 2020.

Program	Prior Authorization
Change Control	
Date	Change
12/2018	New program
4/2019	Added step through Lynparza since Lynparza will be the preferred PARP inhibitor for breast cancer on 7/1/19.
12/2019	Annual review. Updated references.
12/2020	Annual review. Updated references.