

**Commercial/Healthcare Exchange PA Criteria**  
*Effective: February 6<sup>th</sup>, 2019*

**Prior Authorization:** Talzenna

**Products Affected:** Talzenna (talazoparib) oral capsules

**Medication Description:** Talzenna, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated in adult patients with deleterious or suspected deleterious germline BReast CAncer susceptibility gene (gBRCA)-mutated human epidermal growth factor receptor 2 (HER2)-negative locally-advanced or metastatic breast cancer.<sup>1</sup> Talzenna was approved with an FDA-approved companion diagnostic test.

**Covered Uses:** Deleterious or suspected deleterious germline breast cancer susceptibility gene (BRCA)-mutated (gBRCAm) human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer.

**Exclusion Criteria:** N/A

**Required Medical Information:**

1. Diagnosis
2. Documentation of the presence of germline BRCA mutation
3. Human epidermal growth factor receptor 2 (HER2) status.

**Age Restrictions:** 18 years of age or older

**Prescriber Restrictions:** Prescribed by, or in consultation with, an oncologist.

**Coverage Duration:**

Initial: 12 months

Continuation: 3 years

**Other Criteria:**

- A. Patient has a diagnosis of locally advanced or metastatic breast cancer; AND
- B. Patient has germline BRCA mutation-positive breast cancer; AND
- C. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer.

**References:**

1. Talzenna™ capsules [prescribing information]. New York, NY: Pfizer Inc.; October 2018.

**Policy Revision history**

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	01/01/2019

Last Res. July 1, 2019

2	Update	Added continuation coverage duration of 3 years	Coverage Duration	7/1/2019
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