

SPECIALTY GUIDELINE MANAGEMENT

TALZENNA (talazoparib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indication

Talzenna is indicated for the treatment of adult patients with 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. Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.

B. Compendial Uses

1. Recurrent or metastatic human epidermal growth factor receptor 2 (HER2)-negative, BRCA 1/2-germline mutated breast cancer that is hormone receptor-negative, or hormone receptor-positive disease with visceral crisis or endocrine therapy refractory.
2. Recurrent or metastatic HER2-positive BRCA1/2-germline mutated breast cancer that is hormone receptor negative, or hormone receptor positive with or without endocrine therapy.

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: BRCA mutation testing results.

III. CRITERIA FOR INITIAL APPROVAL

Breast cancer

Authorization of 12 months may be granted for treatment of locally advanced, recurrent, or metastatic breast cancer as a single agent in members with deleterious or suspected deleterious germline BRCA mutations.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Talzenna [package insert]. New York, NY: Pfizer Inc.; October 2020.

Reference number(s)
2782-A

2. The NCCN Drugs & Biologics Compendium 2020 National Comprehensive Cancer Network, Inc.
<https://www.nccn.org>. Accessed December 2, 2020.