Reference number(s)
2782-A

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.

FDA-Approved Indications
Talzenna is indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (*gBRCAm*) HER-2 negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.

All other indications are considered experimental/investigational and are not a covered benefit.

II. CRITERIA FOR INITIAL APPROVAL

Breast cancer
Authorization of 12 months may be granted for the treatment of human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in members with deleterious or suspected deleterious germline BRCA mutations as detected by an FDA-approved companion diagnostic test.

III. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must meet all initial authorization criteria.

IV. REFERENCES

1. Talzenna [package insert]. New York, NY: Pfizer Inc.; October 2018.