

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Talzenna Prior Authorization Policy

- Talzenna™ (talazoparib capsules – Pfizer)

REVIEW DATE: 11/11/2020

OVERVIEW

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**.¹

GUIDELINES

The National Comprehensive Cancer Network (NCCN) guidelines on breast cancer (version 6.2020 – September 8, 2020) recommends Talzenna as a category 1 preferred regimen for patients with recurrent or metastatic breast cancer which are HER2-negative and have germline *BRCA1/2* mutation.² Lynparza® (olaparib tablets) is another category 1 recommended option in this setting. The guidelines note that although Talzenna and Lynparza are FDA-approved for HER2-negative disease, the NCCN Panel supports use of these agents in any subtype associated with a germline *BRCA1* or *BRCA2* mutation.

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Talzenna. All approvals are provided for 3 years in duration.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Talzenna is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Breast Cancer.** Approve for 3 years if the patient meets the following criteria (A, B, and C):
 - A. Patient has locally-advanced or metastatic breast cancer; AND
 - B. Patients has germline *BRCA* mutation-positive disease; AND
 - C. Patient has human epidermal growth factor receptor 2 (HER2)-negative breast cancer.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Talzenna is not recommended in the following situations:

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Talzenna™ capsules [prescribing information]. New York, NY: Pfizer; March 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 6.2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on November 9, 2020.