

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Talzenna Prior Authorization Policy

- Talzenna® (talazoparib capsules – Pfizer)

REVIEW DATE: 11/30/2022

OVERVIEW

Talzenna, a poly (ADP-ribose) polymerase (PARP) inhibitor, is indicated in adults with deleterious or suspected deleterious germline BReast CAncer susceptibility gene (*BRCA*)-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 4.2022 – June 21, 2022) recommends Talzenna as a category 1 preferred regimen for patients with recurrent unresectable (local or regional) or Stage IV disease breast cancer with 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.²

POLICY STATEMENT

Prior Authorization is recommended for prescription benefit coverage of Talzenna. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Breast Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C and D):
 - A) Patient is \geq 18 years of age; AND
 - B) Patient has recurrent or metastatic breast cancer; AND
 - C) Patients has germline *BRCA* mutation-positive disease; AND
 - D) 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; September 2021.

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2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (version 4.2022 – June 21, 2022). © 2022 National Comprehensive Cancer Network. Available at: <http://www.nccn.org>. Accessed on November 28, 2022.