Talzenna (talazoparib)

NOTICE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

BENEFIT APPLICATION

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

DESCRIPTION

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 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 (HER-2) negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.

Compendial Uses

1. Recurrent or metastaic 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.

POLICY

Documentation

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

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 germline BRCA mutatations.

Continuation of Therapy

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

Dosing and Administration

Approvals may be subject to age and dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

PROCEDURES AND BILLING CODES

To report provider services, use appropriate CPT* codes, Alpha Numeric (HCPCS level 2) codes, Revenue codes, and/or ICD diagnostic codes.

REFERENCES

- Talzenna [package insert]. New York, NY: Pfizer Inc.; September 2019.
- The NCCN Drugs & Biologics Compendium® © 2019 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 13, 2020.
- National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Breast Cancer. Version 3.2018. https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed January 13, 2020.

POLICY HISTORY

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