Clinical Policy: Talazoparib (Talzenna)

Reference Number: PA.CP.PHAR.409
Effective Date: 01.19
Last Review Date: 01.19 Revision Log

Description
Talazoparib (Talzenna™) is a poly (ADP-ribose) polymerase (PARP) inhibitor.

FDA Approved Indication(s)
Talzenna is indicated for the treatment of adult patients with deleterious or suspected deleterious germline BRCA-mutated (gBRCAm) HER2-negative locally advanced or metastatic breast cancer. Select patients for therapy based on an FDA-approved companion diagnostic for Talzenna.

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Talzenna is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of metastatic breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Documentation of human epidermal growth factor receptor 2 (HER2)-negative disease;
5. Mutations in the BRCA genes as detected by an FDA-approved test (e.g., BRACAnalysis CDx);
6. Dose does not exceed 1 mg (1 capsule) per day.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

II. Continued Therapy

A. Breast Cancer (must meet all)**:**

1. Currently receiving medication via Pennsylvania Health and Wellness benefit or member has previously met all initial approval criteria or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, new dose does not exceed 1 mg (1 capsule) per day.

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. Currently receiving medication via Pennsylvania Health and Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53.

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy – PA.CP.PMN.53 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

ADP: adenosine diphosphate
BRCA: breast cancer gene
gBRCAm: mutations in the germline BRCA genes
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2
HR: hormone receptor
NCCN: National Comprehensive Cancer Network
PARP: poly (ADP-ribose) polymerase

Appendix B; Therapeutic Alternatives

Not applicable

Appendix C: Contraindications/Boxed Warnings

None reported

Appendix D: General Information

- The FDA approved indication for talazoparib includes using the diagnostic tool BRACAnalysis CDx™ by Myriad Genetic Laboratories. It is available at http://www.fda.gov/companiondiagnostics.
- NCCN recommended uses: Breast cancer, as a single agent for recurrent or stage IV (M1) HER2-negative, BRCA 1/2-germline mutated disease:
  - With symptomatic visceral disease or visceral crisis, or
  - That is hormone receptor-negative, or hormone receptor-positive and endocrine therapy refractory.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	1 mg PO QD	1 mg/day

VI. Product Availability

Capsules: 0.25 mg, 1 mg

VII. References

1. Talzenna Prescribing Information. New York NY: Pfizer; October 2018. Available at: www.talzenna.com/. Accessed November 7, 2018.
2. Litton JK, Rugo HS, Ettl J, et al. Talazoparib in patients with advanced breast cancer and a germline BRCA mutation. N Engl J Med. 2018; 379:753-763.
3. National Comprehensive Cancer Network. Breast Cancer. Version 3.2018. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed November 7, 2018.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.19	