Clinical Policy: Talazoparib (Talzenna)

Reference Number: ERX.SPA.322
Effective Date: 03.01.19
Last Review Date: 02.22
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

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) human epidermal growth factor receptor 2 (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.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Talzenna is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

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

1. Diagnosis of recurrent, locally advanced, or metastatic breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. For brand Talzenna requests, medical justification supports inability to use generic talazoparib, if available (e.g., contraindications to excipients);
5. Documentation of HER2-negative disease;
6. Mutations in the BRCA genes;
7. Member must use formulary agent, Lynparza®, unless contraindicated or clinically significant adverse effects are experienced;
8. Member has not previously received a PARP inhibitor (e.g., Lynparza, Rubraca®, Zejula®);
9. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg (1 capsule) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 6 months
Commercial – Length of Benefit

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

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

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Talzenna for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. For brand Talzenna requests, medical justification supports inability to use generic talazoparib, if available (e.g., contraindications to excipients);
4. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 1 mg (1 capsule) per day;
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Medicaid – 12 months
Commercial – Length of Benefit

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

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 – ERX.PA.01 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.
- There is insufficient data regarding the use of consecutive PARP inhibitors. Most PARP inhibitor pivotal trials excluded prior PARP inhibitor use, the NCCN does not make any explicit recommendations (other than for ovarian cancer, where they state data is limited), and there are no randomized controlled trials evaluating such use.

V. Dosage and Administration

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

Indication	Dosing Regimen	Maximum Dose
	For patients with moderate renal impairment (CrCl 30 – 59 mL/min): 0.75 mg PO QD For patients with severe renal impairment (CrCl 15 – 29 mL/min): 0.5 mg PO QD	

VI. Product Availability
Capsules: 0.25 mg, 0.5 mg, 0.75 mg, 1 mg

VII. References
1. Talzenna Prescribing Information. New York NY: Pfizer; September 2021. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2021/211651s008lbl.pdf. Accessed October 4, 2021.
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 8.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed October 4, 2021.
4. Talazoparib In: National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed October 4, 2021.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	11.27.18	02.19
1Q 2020 annual review: no significant changes; added recurrent or locally advanced breast cancer to align with NCCN and FDA-approved indication; added off-label dosing; added Commercial line of business with Length of Benefit approval durations; references reviewed and updated.	10.29.19	02.20
Added requirement for no prior PARP inhibitor use.	06.23.20	08.20
1Q 2021 annual review: updated dose limits given renal impairment adjustments would exceed 1 capsule per day; references reviewed and updated.	10.15.20	02.21
1Q 2022 annual review: added redirection to Lynparza per formulary status; RT4: added new strengths (0.5 mg and 0.75 mg) and removed dose optimization language for renal impairment; added new template language regarding redirection to generic if available for oral oncology agents; references reviewed and updated.	10.04.21	02.22

Important Reminder
This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.