RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	talazoparib
Policy Number:	RxA.514
Drug(s) Applied:	Talzenna®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

Background

Talazoparib (Talzenna®) is a poly (ADP-ribose) polymerase (PARP) inhibitor. It 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®.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
Talazoparib (Talzenna®)	Breast cancer	1 mg PO once daily	1 mg/day

Dosage Forms

- Capsules: 0.25 mg, 1 mg

Clinical Policy

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

I. Initial Approval Criteria

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

1. Diagnosis of locally advanced, or metastatic breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age 18 years or more;
4. Documentation of human epidermal growth factor receptor 2 (HER2)-negative disease;
5. Mutations in the BRCA genes;
6. Dose does not exceed 1 mg (1 capsule) per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

II. Continued Therapy Approval

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

1. Member is currently receiving medication that has been authorized by RxAdvance, 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. If request is for a dose increase, new dose does not exceed 1 mg (1 capsule) per day.

Approval duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

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
- Contraindication(s):
  - None reported

- Boxed Warning(s):
  - None reported

APPENDIX D: General Information
- The FDA approved indication for talazoparib includes using the diagnostic tool BRAC Analysis 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.
- Therapeutic Drug Monitoring:
  - Hemoglobin less than 8 g/dL: Hold talazoparib therapy and monitor blood counts weekly. When hemoglobin recovers to 9 g/dL or higher, reduce the daily dose of talazoparib by 0.25 mg and resume therapy.
  - Neutrophil count less than 1,000 cells/mm^3: Hold talazoparib therapy and monitor blood counts weekly. When neutrophils recover to 1,500 cells/mm^3 or higher, reduce the daily dose of talazoparib by 0.25 mg and resume therapy.
  - Platelet count less than 50,000 cells/mm^3: Hold talazoparib therapy and monitor blood counts weekly. When the platelet count recovers to 75,000 cells/mm^3 or higher, reduce the daily dose of talazoparib by 0.25 mg and resume therapy.

References

1. Talzenna® Prescribing Information. New York, NY: Pfizer Labs; March 2020. Available at: www.talzenna.com. Accessed September 25, 2020.
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. 2020; 379:753-763. Accessed September 25, 2020.
3. National Comprehensive Cancer Network. Breast Cancer. Version 6.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 25, 2020.
4. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed September 25, 2020.
5. Talazoparib, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed September 25, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Initial approval criteria I.A.1 was updated "Diagnosis of locally advanced, or metastatic breast cancer" 3. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication that has been authorized by RxAdvance…". 4. Approval duration was updated from Length of benefit to 12 months for Initial and continued approval criteria. 5. Appendix D: TDM was added. 6. References were updated.	09/25/2020	12/07/2020