Clinical Policy Title:	talazoparib
Policy Number:	RxA.514
Drug(s) Applied:	Talzenna®
Original Policy Date:	03/06/2020
Last Review Date:	08/28/2024
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

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

1. Diagnosis of recurrent and metastatic breast cancer;
2. Documentation of human epidermal growth factor receptor 2 (HER2)-negative disease;
3. Mutations in the BRCA genes;
4. Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Zejula®).

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

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

1. Auto-approval based on lookback functionality within the past 120 days as a proxy for member responding positively to therapy.

Approval duration

All Lines of Business (except Medicare): 12 months

References

1. 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. Available at: https://www.nejm.org/doi/full/10.1056/nejmoa1802905. Accessed August 28, 2024.
2. National Comprehensive Cancer Network. Breast Cancer. Version 4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed August 28, 2024.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Initial approval criteria I.A.1 was updated "Diagnosis of locally advanced, or metastatic breast cancer" 2. Continued therapy criteria II.A.1 was rephrased to "Currently receiving medication	09/25/2020	12/07/2020

that has been authorized by RxAdvance…". 3. Approval duration was updated from Length of benefit to 12 months for Initial and continued approval criteria. 4. References were updated.		
Policy was reviewed: 1. References were reviewed and updated.	09/21/2021	12/07/2021
Policy was reviewed: 1. Initial Approval Criteria, I.A.1: Updated diagnostic criteria from Diagnosis of locally advanced, or metastatic breast cancer to Diagnosis of recurrent and metastatic breast cancer. 2. Initial Approval Criteria, I.A.6: Updated to include new prior treatment criteria Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Zejula®). *Prescribed regimen must be FDA-approved or recommended by NCCN. 3. References were reviewed and updated.	09/07/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Removed age restrictions. 2. Removed prescriber restrictions. 3. Removed dose restrictions. 4. Updated Continued therapy approval with auto-approval based on lookback functionality within the past 120 days. 5. Removed reauthorization requirement for positive response to therapy. 6. Updated approval duration verbiage. 7. References were reviewed and updated.	08/28/2024	09/13/2024