

Clinical Policy Title:	talazoparib
Policy Number:	RxA.514
Drug(s) Applied:	Talzenna®
Original Policy Date:	03/06/2020
Last Review Date:	12/11/2025
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 locally advanced or metastatic breast cancer;
2. Documentation of human epidermal growth factor receptor 2 (HER2)-negative disease;
3. Patient has germline BRCA mutation-positive disease

B. Prostate Cancer (must meet all):

1. Diagnosis of HRR Gene-mutated metastatic castration-resistant prostate cancer;
2. Used in combination with enzalutamide;
3. Patient meets ONE of the following (i or ii):
 - i. The medication is concurrently used with a gonadotropin-releasing hormone (GnRH) analog;
 - ii. Patient has had a bilateral orchiectomy.

Approval duration

All Lines of Business (except Medicare): 12 months

II. Continued Therapy Approval

A. All indications (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

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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 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. 	09/25/2020	12/07/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. References were reviewed and updated. 	09/21/2021	12/07/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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
<p>Policy was reviewed.</p>	10/19/2023	10/19/2023
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 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
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Reformatted policy to include all FDA approved indications. 	6/26/2025	N/A
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Updated continuation language. 	8/11/2025	N/A

Policy reviewed	12/11/2025	12/11/2025
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