Clinical Policy Title:	talazoparib
Policy Number:	RxA.514
Drug(s) Applied:	Talzenna®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
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. 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;
6. Member has not previously received a PARP inhibitor (e.g., Lynparza®, Rubraca®, Zejula®);
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg 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
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, request meets one of the following (a or b):*
   a. Dose does not exceed 1 mg 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
Commercial: 12 months
Medicaid: 12 months

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.

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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 September 09, 2022.
2. National Comprehensive Cancer Network. Breast Cancer. Version 4.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 09, 2022.

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 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
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

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