

Clinical Policy Title:	tucatinib
Policy Number:	RxA.647
Drug(s) Applied:	Tukysa®
Original Policy Date:	09/14/2020
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 advanced, unresectable, or metastatic HER2-positive breast cancer;
2. Prescribed in combination with trastuzumab and capecitabine;
3. Member has received one or more prior anti-HER2-based regimens (with trastuzumab, pertuzumab, and ado-trastuzumab emtansine (TDM1) separately or in combination) in the metastatic setting.

Approval Duration

All lines of business (except Medicare): 12 months, Split-fill

B. Colorectal Cancer (must meet all):

1. Diagnosis of unresectable, or metastatic colon cancer
2. Disease is both of the following (a and b):
 - a. HER2 positive (amplified);
 - b. RAS (i.e., both KRAS and NRAS) wild-type;
3. Prescribed in combination with trastuzumab;
4. Disease has progressed following a fluoropyrimidine- (e.g., 5-fluorouracil, capecitabine), oxaliplatin, or irinotecan-based regimen.

Approval Duration

All lines of business (except Medicare): 12 months, Split-fill

II. Continued Therapy Approval

A. All Indications in Section I (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. National Comprehensive Cancer Network Guidelines. Breast Cancer Version 2.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed June 14, 2024.
2. National Comprehensive Cancer Network Guidelines. Central Nervous System Cancer Version 1. 2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed June 14, 2024.

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.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/11/2020	09/14/2020
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A.1 was updated from “Diagnosis of recurrent, locally advanced, or metastatic breast cancer” to “Diagnosis of any one of the following (a or b)...”. 2. Initial Approval Criteria I.A.1.b was updated to include “Brain metastases related to breast cancer...”. 3. Initial Approval Criteria I.A.2 was updated to include “Documentation of advanced, unresectable, or metastatic HER2-positive breast cancer...”. 4. Initial Approval Criteria I.A.4 was updated to remove “Documentation of human epidermal growth factor receptor 2 (HER2)-negative disease...”. 5. Initial Approval Criteria I.A.5 was updated to include “Prescribed in combination with trastuzumab and capecitabine...”. 6. Initial Approval Criteria I.A.6 was updated to include “Member has received one or more prior anti-HER2-based regimens...”. 7. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 8. Continued Therapy Approval Criteria II.A.3.b was updated to include “Dose is supported by practice guidelines or peer-reviewed...”. 9. References were reviewed and updated. 	07/02/2021	09/14/2021
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria I.A: Updated to remove diagnosis of breast cancer or brain metastasis related to breast cancer. 2. References were reviewed and updated. 	04/18/2022	07/18/2022
<p>Policy was reviewed:</p> <ol style="list-style-type: none"> 1. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, 	03/01/2023	04/13/2023

Unresectable or Metastatic Colorectal Cancer. 2. References were reviewed and updated.		
Policy was reviewed: 1. Initial Approval Criteria, I.A: Updated Approval duration from 6 months to 12 months or duration of request, whichever is less for Commercial. 2. Continued Therapy Approval Criteria II.A: Updated from Breast Cancer to All Indications in Section I. 3. References were reviewed and updated.	05/05/2023	07/13/2023
Policy was reviewed.	10/19/2023	10/19/2023
Policy was reviewed: 1. Age Criteria Removed. 2. Dose Criteria Removed. 3. Approval Duration Updated. 4. Continuation Criteria Updated. 5. References were reviewed and updated.	6/14/2024	6/14/2024
Policy was reviewed.	12/05/2024	N/A
Policy reviewed.	12/11/2025	12/11/2025