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| **Clinical Policy Title:** | tucatinib |
| **Policy Number:** | RxA.647 |
| **Drug(s) Applied:** | Tukysa® |
| **Original Policy Date:** | 09/14/2020 |
| **Last Review Date:** | 6/14/2024 |
| **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 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.

| Review/Revision History | Review/Revision Date | P&T Approval Date |
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| Policy established. | 08/11/2020 | 09/14/2020 |
| Policy was reviewed:<br>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)…”.<br>2. Initial Approval Criteria I.A.1.b was updated to include “Brain metastases related to breast cancer…”.<br>3. Initial Approval Criteria I.A.2 was updated to include “Documentation of advanced, unresectable, or metastatic HER2-positive breast cancer…”.<br>4. Initial Approval Criteria I.A.4 was updated to remove “Documentation of human epidermal growth factor receptor 2 (HER2)-negative disease…”.<br>5. Initial Approval Criteria I.A.5 was updated to include “Prescribed in combination with trastuzumab and capecitabine…”.<br>6. Initial Approval Criteria I.A.6 was updated to include “Member has received one or more prior anti-HER2-based regimens…”.<br>7. Continued Therapy Approval Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...".<br>8. Continued Therapy Approval Criteria II.A.3.b was updated to include “Dose is supported by practice guidelines or peer-reviewed…”.<br>9. References were reviewed and updated. | 07/02/2021 | 09/14/2021 |
| Policy was reviewed:<br>1. Initial Approval Criteria I.A: Updated to remove diagnosis of breast cancer or brain metastasis related to breast cancer.<br>2. References were reviewed and updated. | 04/18/2022 | 07/18/2022 |
| Policy was reviewed:<br>1. Initial Approval Criteria, I.B: Updated to include approval criteria for indication, | 03/01/2023 | 04/13/2023 |

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