RXADVANCE
2 Park Central Drive
Southborough, MA 01772

Clinical Policy Title:	tucatinib
Policy Number:	RxA.647
Drug(s) Applied:	Tukysa™
Original Policy Date:	09/14/2020
Last Review Date:	09/14/2020
Line of Business Policy Applies to:	All lines of business

Background

TUKYSA is a kinase inhibitor indicated in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

HER2-positive breast cancer, which makes up approximately one-fifth of breast cancers, has too much of a protein called human epidermal growth factor receptor 2 (HER2), which promotes the growth of cancer cells. More than 25% of women with metastatic HER2-positive breast cancer will develop brain metastases.

Dosing Information

Drug Name	Indication	Dosing Regimen	Maximum Dose
tucatinib (Tukysa)	Combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.	300 mg by mouth twice daily in combination with trastuzumab and capecitabine	300 mg twice daily

Dosage Forms

- Tablets: 50 mg and 150 mg

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Breast Cancer (must meet all):

1. Diagnosis of recurrent, locally advanced, or 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. Dose does not exceed 300 mg twice daily.

Approval Duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Breast Cancer (must meet all):

1. Currently receiving medication that has been authorized by RxAdvance or member has previously met initial approval criteria listed in this policy;
2. Member is responding positively to therapy;
3. If request for a dose increase, new dose does not exceed 300 mg twice daily

Approval Duration
Commercial: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2

APPENDIX B: Therapeutic Alternatives
Not applicable.

APPENDIX C: Contraindications/Boxed Warnings

- Contraindication(s):
  - None
- Boxed Warning(s):
  - None

APPENDIX D: General Information
NCCN Guidelines Version 4.2020 Breast Cancer

- Added tucatinib + trastuzumab + capecitabine (category 1) as an other recommended regimen for HER2-positive disease, with the following footnote: For adult patients with advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

References

1. Tukysa (tucatinib) [prescribing information]. Bothell, WA: Seattle Genetics, Inc.; April 2020. Accessed on June 30, 2020.
2. Breast Cancer (Version 4.2020). NCCN Clinical Practice Guidelines in Oncology. National Comprehensive Cancer Network (NCCN). Accessed on June 30, 2020.

3. Seattle Genetics Announces U.S. FDA Approval of TUKYSA™ (tucatinib) for People with Advanced Unresectable or Metastatic HER2-Positive Breast Cancer. Seattle Genetics. 2020. Available at https://investor.seattlegenetics.com/press-releases
4. Murthy RK, Loi S, Okines A, et al. Tucatinib, Trastuzumab, and Capecitabine for HER2-Positive Metastatic Breast Cancer. N Engl J Med 2020; 382:597.
5. Baselga J, Cortés J, Kim SB, et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. N Engl J Med 2012; 366:109.
6. Swain SM, Baselga J, Kim SB, et al. Pertuzumab, trastuzumab, and docetaxel in HER2-positive metastatic breast cancer. N Engl J Med 2015; 372:724.
7. Swain SM, Miles D, Kim SB, et al. Pertuzumab, trastuzumab, and docetaxel for HER2-positive metastatic breast cancer (CLEOPATRA): end-of-study results from a double-blind, randomised, placebo-controlled, phase 3 study. Lancet Oncol 2020; 21:519.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	08/11/2020	09/14/2020