Reference number(s)
3782-A

SPECIALTY GUIDELINE MANAGEMENT

TUKYSA (tucatinib)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
1. Tukysa is 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.
2. Tukysa is indicated in combination with trastuzumab for the treatment of adult patients with RAS wild-type HER2-positive unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

B. Compendial Uses
1. Breast Cancer – recurrent unresectable disease
2. Breast Cancer – no response to preoperative systemic therapy
3. Colorectal Cancer – BRAF wild-type disease

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Documentation of human epidermal growth factor receptor 2 (HER2) status, where applicable
B. Documentation of RAS mutation status, where applicable
C. Documentation of BRAF mutation status, where applicable

III. CRITERIA FOR INITIAL APPROVAL

A. Breast Cancer
Authorization of 12 months may be granted for treatment of HER2-positive breast cancer in combination with trastuzumab and capecitabine when any of the following criteria are met:
1. As subsequent therapy for members with no response to preoperative systemic therapy, recurrent unresectable, advanced unresectable, or metastatic disease including limited or extensive brain metastases; or
2. As initial therapy for members with small asymptomatic brain metastases

B. Colorectal Cancer
Authorization of 12 months may be granted for treatment of unresectable, advanced, or metastatic colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, when all of the following criteria are met:

1. The member has HER2-positive disease
2. The disease is negative (wild-type) for RAS (KRAS and NRAS) and BRAF mutations
3. The requested medication will be used in combination with trastuzumab
4. The member is not appropriate for intensive therapy or has experienced disease progression

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Tukysa [package insert]. Bothell, WA: Seagen, Inc.; January 2023.
2. The NCCN Drugs & Biologics Compendium® © 2023 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed January 27, 2023.
3. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Colon Cancer. Version 3.2022. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed January 27, 2023.
4. National Comprehensive Cancer Network. NCCN Clinical Practice Guidelines in Oncology: Anal Carcinoma. Version 1.2023. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf. Accessed January 23, 2023.