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
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.

B. Compendial Uses
Breast Cancer – recurrent unresectable disease

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

II. DOCUMENTATION

Submission of human epidermal growth factor receptor 2 (HER2) status is necessary to initiate the prior authorization review.

III. CRITERIA FOR INITIAL APPROVAL

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 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

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; April 2020.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed November 24, 2021.