

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 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.

B. Compendial Uses

Treatment of breast cancer in combination with capecitabine and trastuzumab for recurrent or advanced unresectable or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-positive disease, including patients with brain metastasis, who have received one or more lines of prior HER2-targeted therapy in the metastatic setting.

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 recurrent or advanced unresectable or metastatic HER2-positive breast cancer in combination with trastuzumab and capecitabine when the member has received one or more prior anti-HER2-based regimens in the metastatic setting.

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: Seattle Genetics, Inc; April 2020.

Reference number(s)
3782-A

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