

Commercial/Healthcare Exchange PA Criteria

Effective: July 8, 2020

Prior Authorization: Tukysa

Products Affected: Tukysa (tucatinib) oral tablets

Medication Description:

Tukysa is an oral tyrosine kinase inhibitor of HER2. In vitro, it inhibits phosphorylation of HER2 and HER3, resulting in inhibition of downstream MAPK and AKT signaling and cell proliferation; it also showed antitumor activity in HER2-expressing cells. In vivo, tucatinib inhibited the growth of HER2-expressing tumors. The combination of tucatinib and trastuzumab showed increased antitumor activity in vitro and in vivo compared to either drug alone. Tukysa is indicated in combination with trastuzumab and capecitabine for the treatment of adult patients with advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer, including patients with brain metastases, who have received one or more prior anti-HER2-based regimens in the metastatic setting.

Covered Uses: Breast cancer, human epidermal growth factor receptor 2-positive, advanced unresectable or metastatic

Exclusion Criteria: N/A

Required Medical Information:

1. Diagnosis
2. Human epidermal growth factor receptor (HER) 2 status
3. Previous medications tried and failed
4. Current medication regimen

Age Restrictions: 18 years of age or older

Prescriber Restriction: Prescribed by, or in consultation with, an oncologist

Coverage Duration: 3 years

Other Criteria:

Breast cancer, human epidermal growth factor receptor 2-positive, advanced unresectable or metastatic

- A. Patient has a diagnosis of advanced unresectable or metastatic HER2-positive breast cancer, including patients with brain metastases; AND
- B. Patient has received one or more prior anti-HER2-based regimens in the metastatic setting (e.g. Perjeta (pertuzumab injection for intravenous use) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Kadcyla (ado-trastuzumab emtansine for intravenous use), trastuzumab + capecitabine, trastuzumab + Tykerb (lapatinib tablets); AND
- C. Tukysa will be used in combination with trastuzumab and capecitabine.

References:

1. Tukysa™ tablets [prescribing information]. Bothell, WA: Seattle Genetics, Inc.; April 2020.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 3.2020 – March 6, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on April 19, 2020.

Policy Revision history

Rev #	Type of Change	Summary of Change	Sections Affected	Date
1	New Policy	New Policy	All	6/11/2020