VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tukysa™ (tucatinib tablets – Seattle Genetics, Inc.)

DATE REVIEWED: 04/22/2020

OVERVIEW

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.[1]

Guidelines

Tukysa is not addressed in the guidelines. According to the National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 3.2020 – March 6, 2020), Enhertu is a recommended therapy, as per its FDA-approved indication after two or more prior HER2-targeted therapies, for the treatment of recurrent or Stage IV metastatic disease that is HER2-positive.[2] Trastuzumab + Perjeta + docetaxel is category 1, preferred regimen; or trastuzumab + Perjeta + paclitaxel (category 2A, preferred). Other recommended regimens include: Kadcyla; trastuzumab + vinorelbine, trastuzumab + capecitabine, Tykerb (lapatinib tablets) + capecitabine, and trastuzumab + Tykerb. For HR+, HER2-positive disease, endocrine therapy options include aromatase inhibitor ± trastuzumab; aromatase inhibitor + trastuzumab ± Tykerb; fulvestrant ± trastuzamab, tamoxifen ± trastuzumab (all category 2A). For premenopausal patients, ovarian ablation or suppression is recommended in addition to endocrine therapy ± trastuzumab.

POLICY STATEMENT

Prior authorization is recommended for prescription benefit coverage of Tukysa. All approvals are provided for the duration noted below.

Automation: None.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Tukysa is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Breast Cancer.** Approve for 3 years if the patient meets ALL of the criteria (A, B, and C):
   - **A)** The patient has advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **B)** The patient has received at least one prior anti-HER2-based regimen in the metastatic setting.
     Note: Examples of anti-HER2-based regimens include 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)** The medication is used in combination with trastuzumab and capecitabine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tukysa has not been shown to be effective or there are limited or preliminary data that are not supportive of general approval for the following conditions.

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

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.