VENTURA COUNTY
HEALTH CARE PLAN

PRIOR AUTHORIZATION POLICY

POLICY: Oncology – Tukysa Prior Authorization Policy
- Tukysa™ (tucatinib tablets – Seattle Genetics)

REVIEW DATE: 04/28/2021

OVERVIEW

Tukysa, a kinase inhibitor, 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

The National Comprehensive Cancer Network (NCCN) breast cancer guidelines (version 3.2021 – March 29, 2021) recommends Tukysa + trastuzumab + capecitabine as a third line (and beyond) option (category 1) for the treatment of recurrent unresectable (local or regional) or stage IV HER2-positive disease. Perjeta® (pertuzumab injection) + trastuzumab + docetaxel (category 1) and Perjeta + trastuzumab + paclitaxel (category 2A) are listed as options for first-line treatment and Kadcyla® (ado-trastuzumab emtansine injection) is a recommended second line agent (category 1). Other third-line (and beyond) options are: Enhertu® (fam-trastuzumab deruxtecan-nxki injection), trastuzumab + docetaxel or vinorelbine, trastuzumab + paclitaxel ± carboplatin, capecitabine + trastuzumab or lapatinib tablets, trastuzumab + lapatinib tablets (without cytotoxic therapy), trastuzumab + other agents, Nerlynx® (neratinib tablets) + capecitabine, and Margenza™ (margetuximab-cmkb injection) + chemotherapy (capecitabine, Halaven® [eribulin injection], gemcitabine, or vinorelbine) [all are category 2A].

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)** Patient has advanced unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease; AND
   - **B)** Patient has received at least one prior anti-HER2-based regimen in the metastatic setting; AND
     Note: Examples of anti-HER2-based regimens include Perjeta (pertuzumab for injection) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Kadcyla (ado-trastuzumab emtansine for injection), capecitabine + trastuzumab or lapatinib tablets, trastuzumab + lapatinib tablets, Enhertu (fam-trastuzumab deruxetecan-nxki for injection), trastuzumab + docetaxel or vinorelbine, Nerlynx (neratinib tablets) + capecitabine, and Margenza (margetuximab-cmkb + chemotherapy (capecitabine, Halaven [eribulin for injection], gemcitabine, or vinorelbine).

C) The medication is used in combination with trastuzumab and capecitabine.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Tukysa is not recommended in the following situations:

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 3.2021 – March 29, 2021). © 2021 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on April 15, 2021.