MEDICAL MUTUAL®

Drug Policy

Policy:	Tukysa (tucatinib)	Annual Review Date: 05/21/2020 Last Revised Date: 05/21/2020

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.

POLICY STATEMENT

This policy involves the use of Tukysa. Prior authorization is recommended for pharmacy benefit coverage of Tukysa. Approval is recommended for those who meet the conditions of coverage in the **Criteria and Initial/Extended Approval** for the diagnosis provided. **Conditions Not Recommended for Approval** are listed following the recommended authorization criteria. Requests for uses not listed in this policy will be reviewed for evidence of efficacy and for medical necessity on a case-by-case basis.

Because of the specialized skills required for evaluation and diagnosis of patients treated with Tukysa as well as the monitoring required for adverse events and long-term efficacy, initial approval requires Tukysa be prescribed by or in consultation with a physician who specializes in the condition being treated. In order to be considered for coverage, Tukysa must be prescribed by or in consultation with a hematologist or oncologist. All approvals for initial therapy are provided for the initial approval duration noted below.

RECOMMENDED AUTHORIZATION CRITERIA

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

1. **Breast Cancer**
   Criteria. *Patient must meet the following criteria*
   - **A.** The patient is 18 years of age or older; AND
   - **B.** The patient has advanced unresectable or metastatic HER2-positive disease; AND
   - **C.** The patient has received at least one prior anti-HER2-based regimen in the metastatic setting (e.g. Perjeta + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel, Kadcyla, Tykerb + trastuzumab, trastuzumab + capecitabine, etc.); AND
   - **D.** Tukysa will be used in combination with trastuzumab and capecitabine

2. **Limited or Extensive Brain Metastases**
   Criteria. *Approve if Tukysa will be used in combination with trastuzumab and capecitabine*

3. **Patients with another indication that is not listed but is cited in the National Comprehensive Cancer Network (NCCN) guidelines as a category 1, 2A, or 2B recommendation**
   Criteria. *Prescriber will provide specific diagnosis for documentation. Approve.*

4. **Patient has been started on Tukysa**
   Criteria. *Approve for an indication or condition addressed as an approval in this document.*

Initial Approval/ Extended Approval.
A) *Initial Approval:* 1 year
B) *Extended Approval:* 1 year

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Tukysa has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

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

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the drug provided or services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

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.
3. Tucatinib. In: DRUGDEX [online database]. Truven Health Analytics; Greenwood Village, CO. Last updated 23 April 2020. Accessed 21 May 2020.
4. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on 21 May 2020.