UnitedHealthcare Community Plan

Clinical Pharmacy Program Guidelines for Tukysa

Program	Prior Authorization
Medication	Tukysa™ (tucatinib)
Markets in Scope	Arizona, California, Hawaii, Nevada, Maryland, New Jersey, New York, New York EPP, Pennsylvania- CHIP, Rhode Island, South Carolina
Issue Date	06/2020
Pharmacy and Therapeutics Approval Date	06/2020
Effective Date	08/2020

1. Background:

Tukysa™ (tucatinib) is a kinase inhibitor indicated in combination with trastuzumab and capecitabine for 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]

2. Coverage Criteria:

A. <u>Breast Cancer</u>

1. **<u>Initial Authorization</u>**

a. **Tukysa** will be approved based on **<u>all</u>** of the following criteria:

(1) Diagnosis of breast cancer

-AND-

(2) Disease is **<u>one</u>** of the following:
   a. Advanced unresectable
   b. Metastatic

-AND-

(3) Disease is human epidermal growth factor receptor 2 (HER2)-positive

-AND-

(4) Patient has been previously treated with an anti-HER2-based regimen in the metastatic setting (e.g., trastuzumab (Herceptin, Kanjinti), pertuzumab (Perjeta), ado-trastuzumab emtansine (T-DM1)

-AND-

(5) Used in combination with trastuzumab (e.g., Herceptin, Kanjinti, Ontruzant) and capecitabine (Xeloda)

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tukysa** will be approved based on the following criterion:

(1) Patient does not show evidence of progressive disease while on **Tukysa** therapy

Authorization will be issued for 12 months.

B. NCCN Recommended Regimens

1. Initial Authorization

a. **Tukysa** will be approved for uses not outlined above if supported by The National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium.

Authorization will be issued for 12 months.

2. Reauthorization

a. **Tukysa** will be approved based on the following criterion:

(1) Documentation of positive clinical response to Tukysa therapy

Authorization will be issued for 12 months.

3. Additional Clinical Rules:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may be in place.

4. References:

1. Tukysa™ [package insert]. Bothell, WA: Seattle Genetics, Inc. April 2020.
2. The NCCN Drugs and Biologics Compendium (NCCN Compendium™). Available at www.nccn.org. Accessed May 12, 2020.

Program	Program type – Prior Authorization
Change Control	
Date	Change
6/2020	New program.