Kansas City

An Independent Licensee of the Blue Cross and Blue Shield Association

Tukysa (tucatinib)

Policy Number: 5.01.724
Origination: 10/2020
Last Review: 10/2022
Next Review: 10/2023

Policy

Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for **Tukysa (tucatinib)** when it is determined to be medically necessary because the criteria shown below are met.

When Policy Topic is covered

Tukysa (tucatinib) may be considered **medically necessary** when the following criteria are met:

FDA Approved Indication:

1. **Breast Cancer.** Approve for 1 year if patient meets all of the following:
    a. Diagnosis of breast cancer
    b. Disease is one of the following:
        i. Advanced unresectable
        ii. Metastatic
    c. Disease is human epidermal growth factor receptor 2 (HER2)-positive
    d. Used in combination with trastuzumab and capecitabine
    e. Patient has received one or more prior anti-HER2 based regimens (e.g., trastuzumab, pertuzumab, ado-trastuzumab emtansine)
    f. Prescribed by or in consultation with an oncologist

When Policy Topic is not covered

Tukysa (tucatinib) is considered **not medically necessary** when the above criteria is not met and **investigational** for all other uses.

Considerations

Tukysa (tucatinib) requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, local medical policies of other health plans, Medicare (CMS), local providers.

Description of Procedure or Service

Tukysa (tucatinib) is a tyrosine kinase inhibitor of HER2. Tukysa inhibits phosphorylation of HER2 and HER3, resulting in inhibition of downstream MAPK and AKT signaling and cell proliferation and shows anti-tumor activity in HER2 expressing tumor cells. The combination of Tukysa and trastuzumab showed increased anti-tumor activity compared to either drug alone. The safety and effectiveness of Tukysa in pediatric patients less than 18 years of age have not been established (1).

Rationale

Prior authorization is required to ensure the safe, clinically appropriate and cost-effective use of Tukysa (tucatinib) while maintaining optimal therapeutic outcomes.

Warnings and Precautions

- Renal impairment: Tucatinib (in combination with capecitabine and trastuzumab) is not recommended for use in patients with severe renal impairment, as capecitabine is contraindicated in severe renal impairment.
  - Serum creatinine increases: Tucatinib increases serum creatinine by inhibiting renal tubular secretion, but without.affecting glomerular filtration (Murthy 2020; Topletz-Erickson 2020). Serum creatinine elevations initially occurred within the first 3 weeks of treatment (and persisted throughout treatment) and were reversible upon completion of therapy. If persistent serum creatinine elevations are observed, consider alternative markers for renal function evaluation.

References

1. Tukysa Prescribing Information. Seattle Genetics, Inc. Bothell, WA. April 2020.

Billing Coding/Physician Documentation Information

N/A	Oral; Pharmacy benefit

Additional Policy Key Words

N/A

Policy Implementation/Update Information

10/2020	New policy titled Tukysa (tucatinib)
10/2021	Annual review – no changes made
10/2022	Annual review – added Warnings and Precautions