Clinical Policy: Tucatinib (Tukysa)

Reference Number: ERX.SPA.402
Effective Date: 09.01.20
Last Review Date: 08.21
Line of Business: Commercial, Medicaid

Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

Description
Tucatinib (Tukysa™) is a tyrosine kinase inhibitor with anti-human epidermal growth factor receptor 2 (HER2) activity.

FDA Approved Indication(s)
Tukysa is indicated for use in combination with trastuzumab and capecitabine for treatment of adult patients with advanced unresectable or metastatic 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/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

Health plan approved formularies should be reviewed for all coverage determinations. Requirements to use preferred alternative agents apply only when such requirements align with the health plan approved formulary.

It is the policy of health plans affiliated with Envolve Pharmacy Solutions™ that Tukysa is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of advanced unresectable or metastatic breast cancer;
2. Confirmation of HER2 positive disease;
3. Prescribed by or in consultation with an oncologist;
4. Age ≥ 18 years;
5. Failure of a treatment regimen containing one of the following in the metastatic setting, unless clinically significant adverse effects are experienced or all are contraindicated: trastuzumab (Herceptin®), Perjeta® (pertuzumab), Kadcyla® (ado-trastuzumab emtansine);
6. Prescribed in combination with trastuzumab and capecitabine;
7. Request meets one of the following (a or b):*
   a. Dose does not exceed 600 mg (4 tablets) per day;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 6 months

B. Other diagnoses/indications

1. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

II. Continued Therapy

A. Breast Cancer (must meet all)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions, or documentation supports that member is currently receiving Tukysa for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 600 mg (4 tablets) per day;
   b. New dose is supported by practice guideline or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

**Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration:
Commercial – Length of Benefit
Medicaid – 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via a health plan affiliated with Envolve Pharmacy Solutions and documentation supports positive response to therapy.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to ERX.PA.01 if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized).

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off-label use policy – ERX.PA.01 or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Perjeta (pertuzumab) + trastuzumab + docetaxel	Every 21 days: • Perjeta 840 mg IV day 1 followed by 420 mg IV • Herceptin 8 mg/kg IV day 1 followed by 6 mg/kg IV • Docetaxel 75-100 mg/m^2 IV day 1	• Perjeta 840 mg/dose • Herceptin 8 mg/kg/dose • Docetaxel mg/m^2/dose
Kadcyla (ado-trastuzumab emtansine)	3.6 mg/kg IV every 21 days	3.6 mg/kg/dose

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings
None reported

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	300 mg PO BID	600 mg/day

VI. Product Availability

Tablets: 50 mg, 150 mg

VII. References

1. Tukysa Prescribing Information. Bothell, WA: Seattle Genetics, Inc.; April 2020. Available at: www.Tukysa.com. Accessed March 25, 2021.
2. Murthy RK, Loi S, Okines A, et al. Tucatinib, trastuzumab, and capecitabine for HER2-positive metastatic breast cancer. N Engl J Med. 2020 Feb;382(7):597-609.
3. National Comprehensive Cancer Network. Central Nervous System Cancers Version 2.2020. Available at: http://www.nccn.org/professionals/physician_gls/pdf/cns.pdf. Accessed May 6, 2020.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	05.26.20	08.20
3Q 2021 annual review: no significant changes; added requirement for use in combination with trastuzumab and capecitabine per labeling; references reviewed and updated.	03.25.21	08.21

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information.

This Clinical Policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members.