

Tucatinib (TUKYSA) Criteria for Use June 2025

VA Pharmacy Benefits Management Services and National Formulary Committee

The following recommendations are based on medical evidence, clinician input, and expert opinion. The content of the document is dynamic and will be revised as new information becomes available. The purpose of this document is to assist practitioners in clinical decision-making, to standardize and improve the quality of patient care, and to promote cost-effective drug prescribing. THE CLINICIAN SHOULD USE THIS GUIDANCE AND INTERPRET IT IN THE CLINICAL CONTEXT OF THE INDIVIDUAL PATIENT. INDIVIDUAL CASES THAT ARE EXCEPTIONS TO THE EXCLUSION AND INCLUSION CRITERIA SHOULD BE ADJUDICATED AT THE LOCAL FACILITY ACCORDING TO THE POLICY AND PROCEDURES OF ITS P&T COMMITTEE AND PHARMACY SERVICES.

The Product Information should be consulted for detailed prescribing information.

See the VA National PBM-MAP-VPE Monograph on this drug at the [PBM INTRAnet](#) site for further information.

Exclusion Criteria

If the answer to ANY item below is met, then the patient should NOT receive tucatinib.

- Neurologically unstable Central Nervous System (CNS) metastases requiring urgent local intervention
- Unmanageable drug interaction identified
- Known pregnancy
- Lactating

Inclusion Criteria

One of the following criteria must be met.

- In combination with trastuzumab and capecitabine for advanced unresectable or metastatic HER2+ breast cancer who received two or more lines of anti-HER2-based therapy in the metastatic setting
- In combination with trastuzumab and capecitabine for metastatic HER2+ breast cancer with brain metastases who received one or more lines of anti-HER2-based therapy
- In combination with trastuzumab for RAS wild-type HER2+ unresectable or metastatic colorectal cancer that has progressed following treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan- based chemotherapy

Additional Inclusion Criteria *The answers to the following must be fulfilled to meet criteria:*

- Care for the oncologic condition provided by VA or VA Community Care oncology provider
- Goals of care and role of Palliative Care consult have been discussed and documented
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0 to 2

Additional Inclusion Criteria *Select if applicable:*

- For females who can become pregnant: Pregnancy must be excluded prior to receiving tucatinib.
- For females who can become pregnant and males with partners who can become pregnant: Counseling provided on potential risks vs. benefits of treatment and the use of effective contraception during therapy and for one week after stopping treatment.

Other Justification
