

Trastuzumab or Biosimilar Criteria for Use December 2025

VA Pharmacy Benefits Management Services, Medical Advisory Panel, and VISN Pharmacist Executives

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 UTILIZE 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 www.pbm.va.gov or <http://vawww.pbm.va.gov> for further information.

Exclusion Criteria *If the answer to ANY item below is met, then the patient should NOT receive trastuzumab or biosimilar.*

- Clinically significant cardiovascular disease[^]
- Cumulative prior anthracycline exposure > 360 mg/m² of doxorubicin or its equivalent
- Interstitial lung disease or pneumonitis
- Pregnancy
- Lactating

[^] Baseline Left Ventricular Ejection Fraction (LVEF) < 55% via MUGA or echocardiography (<50% if metastatic disease); Uncontrolled hypertension or arrhythmia; Myocardial infarction within prior 6 months; CHF (NYHA Class 3 or 4)

Inclusion Criteria

One of the following must be fulfilled to meet criteria:

- HER2-overexpressing (IHC 3+ or FISH amplification ratio \geq 2.0) breast cancer
- HER2-overexpressing gastric or gastroesophageal junction adenocarcinoma

Additional Inclusion Criteria

All the following must be fulfilled in order to meet criteria:

- Care provided by VA or VA Community Care provider of oncology
- Goals of care and role of Palliative Care consult have been discussed and documented, if appropriate.
- Eastern Cooperative Oncology Group (ECOG) Performance Status 0-2

Additional Inclusion Criteria

Select if applicable:

- For females who can become pregnant: Pregnancy must be excluded prior to receiving trastuzumab or biosimilar
- For females who can become pregnant: Counseling provided on potential risks vs. benefits of treatment and the use of effective contraception during therapy and for 7 months after the last dose

Other Justification

Prepared: March 2015. Updated Nov 2020, Dec 2025 Contact: Berni Heron, VA Pharmacy Benefits Management Services

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Updated versions may be found at <http://www.pbm.va.gov> or <https://vawww.cmopnational.va.gov/cmop/PBM/default.aspx>