

Fam-trastuzumab deruxtecan-nxki (ENHERTU®)**Criteria for Use****June 2022**

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://vaww.pbm.va.gov> for further information.

Exclusion Criteria If the answer to ANY item below is met, then the patient should NOT receive fam-trastuzumab deruxtecan.

- Known hypersensitivity to fam-trastuzumab deruxtecan or its excipients (L-histidine, sucrose, polysorbate 80)
- Clinically significant cardiovascular disease*
- History of, current or suspected interstitial lung disease/pneumonitis
- Clinically active (untreated and symptomatic) Central Nervous System metastases
- Uncontrolled HIV or active hepatitis B or C infection
- Absolute Neutrophil Count < 1500/ mm³ and/or platelet count < 100,000/ mm³
- Creatinine clearance < 30 ml/min
- Total bilirubin > 3 – 10 times Upper Limit of Normal and any AST
- Pregnancy (known pregnancy or positive pregnancy test)
- Breastfeeding

*Baseline Left Ventricular Ejection Fraction (LVEF) < 50% via MUGA or echocardiography; uncontrolled hypertension or arrhythmia; myocardial infarction within prior 6 months; symptomatic Congestive Heart Failure (New York Heart Assoc. Class 2 - 4)

Inclusion Criteria Select one of the following:

- Unresectable or metastatic HER2-positive breast cancer and received a prior anti-HER2-based regimen in metastatic, neoadjuvant or adjuvant setting
- Locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who received a prior trastuzumab-based regimen
- Unresectable or metastatic HER2-low (IHC 1+ or IHC 2+ and ISH negative) breast cancer and received at least 1 prior line of chemotherapy for metastatic disease or with disease recurrence within 6 months of adjuvant 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 - 1

Additional Inclusion Criteria Select if applicable.

- For patients who can become pregnant and patients 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 7 months following the last dose

Other Justification
