Reference number(s)
3470-A

SPECIALTY GUIDELINE MANAGEMENT

ENHERTU (fam-trastuzumab deruxtecan-nxki)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
   1. Breast Cancer
      Enhertu is indicated for the treatment of patients with human epidermal growth factor receptor 2 (HER2)-positive, unresectable or metastatic breast cancer who have previously received treatment with two or more prior anti-HER2 based regimens in the metastatic setting.
   2. Gastric or Gastroesophageal Junction Adenocarcinoma
      Enhertu is indicated for the treatment of patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab-based regimen.

B. Compendial Uses
   1. HER2-positive breast cancer, treatment of recurrent disease
   2. Non-small cell lung cancer with HER2 mutations
   3. HER2-amplified and RAS and BRAF wild-type colorectal cancer

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review: human epidermal growth factor receptor 2 (HER2) status, RAS mutation status (where applicable), BRAF mutation status (where applicable)

III. CRITERIA FOR INITIAL APPROVAL

A. Breast cancer
Authorization of 12 months may be granted for treatment of HER2-positive recurrent, metastatic, or unresectable breast cancer as a single agent in members who have received two or more prior anti-HER2 based regimens,

B. Non-small cell lung cancer
Authorization of 12 months may be granted for treatment of non-small cell lung cancer with HER2 mutations.

C. Colorectal Cancer

Authorization of 12 months may be granted for treatment of colorectal cancer with HER2-amplified and RAS and BRAF wild-type disease as a single agent when either of the following are met:

1. Member is not appropriate for intensive therapy.
2. The requested medication will be used as subsequent therapy for progression of advanced or metastatic disease.

D. Gastric or Gastroesophageal Junction Adenocarcinoma

Authorization of 12 months may be granted for treatment of HER2-positive locally advanced or metastatic gastric or gastroesophageal junction adenocarcinoma as a single agent in members who have received a prior trastuzumab-based regimen.

IV. CONTINUATION OF THERAPY

Authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Enhertu [package insert]. Basking Ridge, NJ: Daiichi Sankyo Inc.; January 2021.
2. The NCCN Drugs & Biologics Compendium® © 2021 National Comprehensive Cancer Network, Inc. https://www.nccn.org. Accessed January 4, 2021.