

POLICY: Oncology – Enhertu[®] (fam-trastuzumab deruxtecan-nxki injection for intravenous use – Daiichi Sankyo, Inc. and AstraZeneca Pharmaceuticals)

DATE REVIEWED: 12/20/2019

OVERVIEW

Enhertu is indicated for the treatment of adult patients with unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting.¹ This indication is approved under accelerated approval based on tumor response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial. Enhertu cannot be substituted for or with trastuzumab or Kadcyla (ado-trastuzumab emtansine).

Guidelines

The NCCN Breast Cancer clinical practice guidelines (version 3.2019 – September 6, 2019) have not yet addressed Enhertu.² For systemic treatment of recurrent or stage IV (M1) disease that is HER2-positive, trastuzumab + Perjeta + docetaxel is category 1, preferred; or trastuzumab + Perjeta + paclitaxel. Other recommended regimens include: Kadcyla; trastuzumab + vinorelbine, trastuzumab + capecitabine, Tykerb (lapatinib tablets) + capecitabine, and trastuzumab + Tykerb. For HR+, HER2-positive disease, endocrine therapy options include aromatase inhibitor ± trastuzumab; aromatase inhibitor + trastuzumab ± Tykerb; Faslodex[®] (fulvestrant for injection) ± trastuzumab, tamoxifen ± trastuzumab (all category 2A). For premenopausal patients, ovarian ablation or suppression is recommended in addition to endocrine therapy ± trastuzumab.

POLICY STATEMENT

Prior authorization is recommended for medical benefit coverage of Enhertu. Approval is recommended for those who meet the Criteria and Dosing for the listed indication(s). Extended approvals are allowed if the patient continues to meet the criteria and dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below.

Because of the of the specialized skills required for evaluation and diagnosis of patients treated with Enhertu, as well as the monitoring required for adverse events and long-term efficacy, approval requires Enhertu to be prescribed by or in consultation with a physician who specializes in the condition being treated.

RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Enhertu is recommended in those who meet the following criteria:

FDA-Approved Indications

1. **Breast Cancer.** Approve for 1 year if the patient meets ALL of the criteria (A, B, and C):
 - A) The patient has unresectable or metastatic human epidermal growth factor receptor 2 (HER2)-positive disease; AND
 - B) The patient has received at least two prior anti-HER2-based regimens in the metastatic setting. **Note:** Examples of anti-HER2-based regimens include Perjeta (pertuzumab injection for intravenous use) + trastuzumab + docetaxel, Perjeta + trastuzumab + paclitaxel; Kadcyla (ado-trastuzumab emtansine for intravenous use), trastuzumab + capecitabine, trastuzumab + Tykerb (lapatinib tablets); AND
 - C) The medication is prescribed by or in consultation with an oncologist.

Dosing. Approve up to 5.4 mg per kg administered as an intravenous infusion not more frequently than once every 3 weeks.

CONDITIONS NOT RECOMMENDED FOR APPROVAL

Enhertu has not been shown to be effective, or there are limited or preliminary data or potential safety concerns that are not supportive of general approval for the following conditions. Rationale for non-coverage for these specific conditions is provided below. (Note: This is not an exhaustive list of Conditions Not Recommended for Approval).

1. Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

REFERENCES

1. Enhertu™ for intravenous use [prescribing information]. Basking Ridge, NJ and Wilmington, DE: Daiichi Sankyo, Inc. and Astrazeneca Pharmaceuticals; December 2019.
2. The NCCN Breast Cancer Clinical Practice Guidelines in Oncology (Version 3.2019 – September 6, 2019). © 2019 National Comprehensive Cancer Network, Inc. Available at: <http://www.nccn.org>. Accessed on December 20, 2019.

HISTORY

Type of Revision	Summary of Changes	Date Reviewed
New policy	New criteria	12/20/2019