SmartHealth Ascension

Fam-Trastuzumab Deruxtecan-Nxki

(Enhertu®) J9358 (1mg)

Covered with prior authorization

Fam-Trastuzumab Deruxtecan-Nxki (Enhertu®) may be authorized when the following criteria are met:

Unresectable or metastatic HER2-positive (HER2+) breast cancer

- Diagnosis has been confirmed by one of the following:
  - Immunohistochemistry (IHC) is 3 +; **OR**
  - In situ hybridization (ISH) positive; **AND**
- Individual is using as monotherapy; **AND**
- Individual has received a prior anti-HER2-based regimen in the metastatic setting; **OR**
- The individual has had disease recurrence during or within six (6) months of completing neoadjuvant or adjuvant therapy.

Unresectable or metastatic HER2-low breast cancer

- Individual is using as monotherapy; **AND**
- Individual has received a prior chemotherapy in the metastatic setting; **OR**
- The individual has had disease recurrence during or within six (6) months of completing adjuvant chemotherapy.

HER2+ gastric or gastroesophageal junction adenocarcinoma

- Diagnosis has been confirmed by one of the following:
  - Immunohistochemistry (IHC) is 3 +; **OR**
  - In situ hybridization (ISH) positive; **AND**
- Individual has received a prior trastuzumab-based regimen.

Unresectable or Metastatic Non-Small Cell Lung Cancer (NSCLC)

- Tumors have activating HER2 (ERBB2) mutations; **AND**
- Individual has received a prior systemic therapy.

Initial authorization is up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and there is documentation of no disease progression or unacceptable toxicity while on treatment.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage.

Enhertu® iis a HER2-directed antibody and topoisomerase inhibitor conjugate indicated for the treatment of:

- Adult patients with unresectable or metastatic HER2-positive breast cancer who have received a prior anti-HER2-based regimen either:
  - In the metastatic setting, or
  - In the neoadjuvant or adjuvant setting and have developed disease recurrence during, or within six months of completing therapy.
- Adult patients with unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer who have received a prior chemotherapy in the metastatic setting or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy.
- Adult patients with unresectable or metastatic non-small cell lung cancer (NSCLC) whose tumors have activating HER2 (ERBB2) mutations, as detected by an FDA approved test, and who have received a prior systemic therapy.
  - This indication is approved under accelerated approval based on objective 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.
- Adult patients with locally advanced or metastatic HER2-positive gastric or gastroesophageal junction adenocarcinoma who have received a prior trastuzumab based regimen.

References

1. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
2. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022.
3. Enhertu (fam-trastuzumab deruxtecan-nxki) for injection, for intravenous use [Prescribing information] Daichi Sankyo, Inc. Basking Ridge, NJ.: 2022.
4. Modi S, Saura C, Yamashita T, et al. Trastuzumab Deruxtecan in Previously Treated HER2-Positive Breast Cancer. N Eng J Med 2019: 10.1056/NEJMoa1914510.
5. National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium®. Fam-trastuzumab deruxtecan-nxki. 2022.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.

Date	Summary of Changes
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.