

Fam-trastuzumab deruxtecan-nxki (Enhertu®)

Place of Service
Office Administration
Outpatient Facility
Administration
Infusion Center Administration

HCPCS: J9358 per 1 mg

Condition listed in policy (see criteria for details)

- [Breast cancer](#)
- [Colorectal cancer \(HER2-amplified\)](#)
- [Esophagogastric junction adenocarcinoma \(HER2-positive\)](#)
- [Gastric cancer \(HER2-positive\)](#)
- [Non-small cell lung cancer \(HER2-mutant\)](#)

AHFS therapeutic class: Antineoplastic agent

Mechanism of action: HER2-targeted antibody-drug conjugate consisting of a humanized anti-HER2 antibody (trastuzumab) covalently linked to a topoisomerase inhibitor (DXd) via a tetrapeptide-based linker

(1) Special Instructions and Pertinent Information

Covered under the Medical Benefit, please submit clinical information for prior authorization review via fax.

(2) Prior Authorization/Medical Review is required for the following condition(s)

All requests for Enhertu® (fam-trastuzumab deruxtecan-nxki) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

Breast cancer

1. One of the following:
 - a. Patient has inflammatory breast cancer and had no response to preoperative systemic therapy
OR
 - b. Disease is unresectable, recurrent unresectable, or metastatic

AND

2. Being used as a single agent, **AND**
3. One of the following:
 - a. HER2-positivity,
OR
 - b. HER2-low disease (IHC 1+, OR IHC 2+ and ISH negative), and either of the following:
 - i. Hormone receptor negative, or
 - ii. Hormone receptor positive and patient has received prior endocrine therapy

Covered Doses

Up to 5.4 mg/kg IV every 3 weeks

Coverage Period

Indefinitely

ICD-10:

C50.011, C50.012, C50.019, C50.021, C50.022, C50.029, C50.111, C50.112, C50.119, C50.121, C50.122, C50.129, C50.211, C50.212, C50.219, C50.221, C50.222, C50.229, C50.311, C50.312, C50.319, C50.321, C50.322, C50.329, C50.411, C50.412, C50.419, C50.421, C50.422, C50.429, C50.511, C50.512, C50.519, C50.521, C50.522, C50.529, C50.611, C50.612, C50.619, C50.621, C50.622, C50.629, C50.811, C50.812, C50.819, C50.821, C50.822, C50.829, C50.911, C50.912, C50.919, C50.921, C50.922, C50.929, Z85.3

Colorectal cancer (HER2-amplified)

1. Disease is advanced, metastatic, unresectable, or inoperable cancer, **AND**
2. HER2 positivity and RAS and BRAF wild type, **AND**
3. Being used as single agent therapy

Covered Doses

Up to 6.4 mg/kg IV every 3 weeks

Coverage Period

Indefinitely

ICD-10:

C17.0-C17.2, C17.8, C17.9, C18.0-C18.9, C78.00-C78.02, C78.6, C78.7, Z85.038, Z85.068

Esophagogastric junction adenocarcinoma (HER2-positive) or Gastric cancer (HER2-positive)

1. Disease is inoperable, unresectable, recurrent, locally advanced or metastatic, **AND**

2. HER2-positivity, **AND**
3. Being used as second line or subsequent therapy for disease conditions above, **AND**
4. Being used as single agent therapy

Covered Doses

Up to 6.4 mg/kg IV every 3 weeks

Coverage Period

Indefinitely

ICD-10:

C15.3-C15.5, C15.8, C15.9, C16.0-C16.6, C16.8, C16.9, D37.1, D37.8, D37.9, Z85.00, Z85.01, Z85.028

Non-small cell lung cancer (HER2-mutant)

1. Recurrent, advanced, unresectable or metastatic disease, **AND**
2. ERBB2 (HER2) mutation, **AND**
3. Being used as a single agent, **AND**
4. ***Effective 10/30/2023 and after.*** Being used as subsequent therapy

Covered Doses

Up to 6.4 mg/kg IV every 3 weeks

Coverage Period

Indefinitely

ICD-10:

C33, C34.00-C34.02, C34.10-C34.12, C34.2, C34.30-C34.32, C34.80-C34.82, C34.90-C34.92

(3) The following condition(s) DO NOT require Prior Authorization/Preservice

All requests for Enhertu® (fam-trastuzumab deruxtecan-nxki) must be sent for clinical review and receive authorization prior to drug administration or claim payment.

(4) This Medication is NOT medically necessary for the following condition(s)

Coverage for a Non-FDA approved indication, requires that criteria outlined in Health and Safety Code § 1367.21, including objective evidence of efficacy and safety are met for the proposed indication.

Please refer to the Provider Manual and User Guide for more information.

(5) Additional Information

How Supplied

- 100 mg (single-use vial)

(6) References

- AHFS®. Available by subscription at <http://www.lexi.com>

- DrugDex®. Available by subscription at <http://www.micromedexsolutions.com/home/dispatch>
- Enhertu® (fam-trastuzumab deruxtecan-nxki) [Prescribing Information]. Basking Ridge, NJ: Daiichi Sankyo Pharmaceuticals, Inc.; 11/2022.
- National Comprehensive Cancer Network. Breast cancer (Version 4.2023). Available at www.nccn.org.
- National Comprehensive Cancer Network. Colon Cancer (Version 2.2023). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Esophageal and Esophagogastric Junction Cancers (Version 2.2023). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Gastric Cancer (Version 1.2023). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Non-small Lung Cell Cancer (Volume 3.2023). Available by subscription at: www.nccn.org.
- National Comprehensive Cancer Network. Rectal Cancer (Version 2.2023). Available by subscription at: www.nccn.org.

(7) Policy Update

Date of last review: 3Q2023

Date of next review: 3Q2024

Changes from previous policy version:

- Section (2): Non-small cell lung cancer –
 - Expanded coverage to include recurrent and advanced disease
 - Effective 10/30/2023, will require use as subsequent therapy

Rationale: NCCN category 2A support

*BSC Drug Coverage Criteria to Determine Medical Necessity
Reviewed by P&T Committee*