Prior Authorization Review Panel

CHC-MCO Policy Submission

A separate copy of this form must accompany each policy submitted for review.
Policies submitted without this form will not be considered for review.

Plan: PA Health & Wellness	**Submission Date: 02/01/2022**
Policy Number: PA.CP.PHAR.456	**Effective Date: 10/2020** **Revision Date: 01/2022**
Policy Name: Fam-trastuzumab Deruxtecan-nxki (Enhertu)	

Type of Submission – Check all that apply:

- ☐ **New Policy**
- ✓ **Revised Policy***
- ☐ **Annual Review - No Revisions**
- ☐ **Statewide PDL -** *Select this box when submitting policies for Statewide PDL implementation and when submitting policies for drug classes included on the Statewide PDL.*

***All revisions to the policy must be highlighted using track changes throughout the document.**

Please provide any changes or clarifying information for the policy below:

1Q 2021 annual review: references reviewed and updated.

Name of Authorized Individual (Please type or print): **Venkateswara R. Davuluri, MD**	**Signature of Authorized Individual:**

Clinical Policy: Fam-trastuzumab Deruxtecan-nxki (Enhertu)

Reference Number: PA.CP.PHAR.456
Effective Date: 10/2020
Last Review Date: 01/2022

Coding Implications
Revision Log

Description
Fam-trastuzumab deruxtecan-nxki (Enhertu®) is a human epidermal growth factor receptor 2 (HER2)-directed antibody and topoisomerase inhibitor conjugate.

FDA Approved Indication(s)
Enhertu is indicated for the treatment of adult patients with

- Unresectable or metastatic HER2-positive breast cancer who have received two or more prior anti-HER2-based regimens in the metastatic setting
- Locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (esophagogastric junction; EGJ) adenocarcinoma who have received a prior trastuzumab-based regimen

Policy/Criteria
Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with PA Health & Wellness® that Enhertu is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Breast Cancer (must meet all)**:**

1. Diagnosis of recurrent, unresectable or metastatic HER2-positive breast cancer;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. One of the following (a or b):
    a. Failure of at least two anti-HER2-based regimens (*see Appendix B*), unless contraindicated or clinically significant adverse effects are experienced;
    b. Progression within 6 months of neoadjuvant or adjuvant therapy (12 months for pertuzumab-containing regimens) (*see Appendix B*);

    **Prior authorization may be required for anti-HER2-based regimens*
5. Request meets one of the following (a or b):*
    a. Dose does not exceed 5.4 mg/kg every 3 weeks;
    b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

    **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 6 months

B. Gastric and Esophagogastric Junction Cancer (must meet all)**:**

1. Diagnosis of HER2-positive gastric or EGJ adenocarcinoma;
2. Prescribed by or in consultation with an oncologist;

3. Age ≥ 18 years;
4. Disease is locally advanced, recurrent or metastatic;
5. Failure of trastuzumab-based regimen (*see Appendix B*);
6. Request meets one of the following (a or b):
   a. Dose does not exceed 6.4 mg/kg every 3 weeks;
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

Approval duration: 6 months

C. Other diagnoses/indications

1. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

II. Continued Therapy

A. Cancer (must meet all)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a, b or c):*
   a. For breast cancer: New dose does not exceed 5.4 mg/kg every 3 weeks;
   b. For gastric or EGJ adenocarcinoma: New dose does not exceed 6.4 mg/kg every 3 weeks;
   c. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (*prescriber must submit supporting evidence*).

   **Prescribed regimen must be FDA-approved or recommended by NCCN*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy or the Continuity of Care policy (PA.LTSS.PHAR.01) applies.
   Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): PA.CP.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – PA.CP.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key
EGJ: esophagogastric junction
FDA: Food and Drug Administration
HER2: human epidermal growth factor receptor 2

NCCN: National Comprehensive Center Network

Appendix B: Therapeutic Alternatives
This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
NCCN examples of systemic therapies for HER2-positive recurrent or metastatic disease • Aromatase inhibitor ± trastuzumab • Aromatase inhibitor ± lapatinib • Pertuzumab + trastuzumab + docetaxel	Varies	Varies
Gastric and Esophagogastric Junction Cancer Trastuzumab-based regimen	8 mg/kg IV q 3 weeks	8 mg/kg

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): interstitial lung disease and pneumonitis; embryo-fetal toxicity

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Breast cancer	5.4 mg/kg IV every 3 weeks	5.4 mg/kg
Gastric cancer	6.4 mg/kg IV every 3 weeks	6.4 mg/kg

VI. Product Availability

Single-dose vial: 100 mg lyophilized powder

VII. References

1. Enhertu Prescribing Information. Basking Ridge, NJ: Daiichi Sankyo, Inc.; January 2021. Available at: www.enhertu.com. Accessed September 13, 2021.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at ww.nccn.org. Accessed September 13, 2021.
3. National Comprehensive Cancer Network. Breast Cancer Version 8.2021. Available at: http://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Accessed September 13, 2021.
4. Modi S, Saura C, Yamashita T, et al. Trastuzumab deruxtecan in previously treated HER2-positive breast cancer. *N Engl J Med*. 2019; doi: 10.1056/NEJMoa1914510.
5. National Comprehensive Cancer Network. Gastric Cancer Version 4.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/gastric.pdf. Accessed September 13, 2021.

Coding Implications
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg

Reviews, Revisions, and Approvals	Date
Policy created	10/2020
1Q 2021 annual review: recurrent breast cancer added per NCCN; added criteria for new FDA-approved gastric cancer indication; updated coding implications; therapeutic alternatives and references reviewed and updated	01/2021
1Q 2022 annual review: references reviewed and updated.	01/2022