Geisinger

POLICIES AND PROCEDURE MANUAL

Policy: MBP 208.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Enhertu (fam-trastuzumab deruxtecan-nxki)

I. Policy:
Enhertu (fam-trastuzumab deruxtecan-nxki)

II. Purpose/Objective:
To provide a policy of coverage regarding Enhertu (fam-trastuzumab deruxtecan-nxki)

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medically Necessary — A service, item, procedure, or level of care compensable under the Medical Assistance program that is necessary for the proper treatment or management of an illness, injury, or disability is one that:

i. Will, or is reasonably expected to, prevent the onset of an illness, condition, injury or disability.
ii. Will, or is reasonably expected to, reduce or ameliorate the physical, mental or developmental effects of an illness, condition, injury or disability.
iii. Will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for Members of the same age.

DESCRIPTION:
Enhertu (fam-trastuzumab deruxtecan-nxki) is a HER2-directed antibody and topoisomerase inhibitor conjugate that binds to HER2 on tumor cells, undergoes internalization and intracellular linker cleavage by lysosomal enzymes, and upon release, causes DNA damage and apoptotic cell death.

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Enhertu (fam-trastuzumab deruxtecan-nxki) will be considered medically necessary for all lines of business when ALL of the following criteria are met:

Breast Cancer

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable or metastatic HER2-positive breast cancer **AND**
- Medical record documentation of one of the following:
    - Documentation of a prior anti-HER2 based therapy in the metastatic setting **OR**
    - Documentation of a prior anti-HER2 based therapy in the neoadjuvant or adjuvant setting AND documentation of disease recurrence during or within 6 months of completing therapy

OR

- Prescription written by a hematologist or oncologist **AND**
- Medical record documentation of patient age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer, as detected by an Food and Drug Administration (FDA)-approved test **AND**
- Medical record documentation that Enhertu will be used as a single agent **AND**
- Medical record documentation of one of the following:
    - Documentation of a prior chemotherapy in the metastatic setting **OR**
    - Documentation of disease recurrence during or within 6 months of completing adjuvant chemotherapy

Gastric Cancer

- Medical record documentation that Enhertu is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of a diagnosis of locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma **AND**
- Medical record documentation of one or more prior trastuzumab-based therapies

Non-Small Cell Lung Cancer

- Medical record documentation that Enhertu is written by a hematologist/oncologist **AND**
- Medical record documentation of age greater than or equal to 18 years **AND**
- Medical record documentation of unresectable or metastatic non-small cell lung cancer (NSCLC) **AND**
- Medical record documentation of tumors that have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test **AND**
- Medical record documentation that Enhertu will be used as a single agent **AND**
- Medical record documentation of a prior systemic therapy

AUTHORIZATION DURATION: Initial approval will be for 12 months or less if the reviewing provider feels it is medically appropriate. Subsequent approvals will be for an additional 12 months or less if the reviewing provider feels it is medically appropriate and will require medical record documentation of continued disease improvement or lack of disease progression. The medication will no longer be covered if patient experiences toxicity or worsening of disease.

Note: The FDA Approved tests for HER2 mutation testing are as follows:

- Breast Cancer: PATHWAY anti-Her2/neu (4B5) Rabbit Monoclonal Primary Antibody (Ventana Medical Systems, Inc.)
- Non-Small Cell Lung Cancer: Guardant360 CDx (Guardant Health, Inc.), Oncomine Dx Target Test (Life Technologies Corporation)

Note: For Medicaid (GHP Family), any requests for services that do not meet criteria set in the PARP will be evaluated on a case-by-case basis.

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 3/17/20

Revised: 3/16/21 (gastric), 7/19/22 (Breast CA metastatic/(neo)adjuvant with prior anti-HER2, Medicaid PARP language), 10/25/22 (Breast CA HER2-low, NSCLC, LOB carve out), 12/23/22 (FDA HER2 testing & note), 12/19/23 (Medicaid business segment)

Reviewed: 1/28/21, 2/22/22

MA UM Committee approval: 12/31/23