BlueCross BlueShield
Federal Employee Program

ENHERTU
(fam-trastuzumab deruxtecan-nxki)

Pre - PA Allowance

None

Prior-Approval Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic HER2-positive (IHC 3+ or ISH positive) breast cancer **AND ONE** of the following:
    a. Patient has received a prior anti-HER2-based regimen in the metastatic setting
    b. Patient has received a prior anti-HER2-based regimen in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within six months of completing therapy
2. Unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer
    a. HER2-low (IHC 1+ or IHC 2+/ISH-) as determined by an FDA-approved test
    b. Patient has **ONE** of the following:
        i. Patient has received prior chemotherapy in the metastatic setting
        ii. Patient developed disease recurrence during or within 6 months of completing adjuvant chemotherapy
        iii. Patient is hormone receptor (HR)-positive and has progressed on one or more endocrine therapies in the metastatic setting
3. Unresectable or metastatic HER2-ultralow (IHC 0 with membrane staining) breast cancer
    a. HER2-ultralow (IHC 0 with membrane staining) as determined by an FDA-approved test
    b. Patient is hormone receptor (HR)-positive and has progressed on one or more endocrine therapies in the metastatic setting
4. Unresectable or metastatic non-small cell lung cancer (NSCLC)
    a. Tumors have activating HER2 (ERBB2) mutations, as detected by an FDA-approved test
    b. Patient has received a prior systemic therapy

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5. Locally advanced or metastatic HER2-positive (IHC 3+ or IHC 2+/ISH positive) gastric or gastroesophageal junction adenocarcinoma
    a. Patient has received a prior trastuzumab-based regimen
6. Unresectable or metastatic HER2-positive (IHC 3+) solid tumor
    a. Patient has received prior systemic treatment
    b. **NO** satisfactory alternative treatment options

AND ALL of the following:

1. Prescriber agrees to monitor for signs and symptoms of interstitial lung disease (ILD)
2. Prescriber agrees to monitor complete blood counts prior to initiation, prior to each dose, and as clinically indicated
3. Prescriber agrees to assess left ventricular ejection fraction (LVEF) prior to initiation and at regular intervals during treatment as clinically indicated
4. Females of reproductive potential **only**: patient has had a negative pregnancy test **AND** patient will be advised to use effective contraception during treatment with Enhertu and for 7 months after the last dose
5. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Enhertu and for 4 months after the last dose

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnoses

Patient must have **ONE** of the following:

1. Unresectable or metastatic HER2-positive (IHC 3+ or ISH positive) breast cancer
2. Unresectable or metastatic HER2-low (IHC 1+ or IHC 2+/ISH-) breast cancer
3. Unresectable or metastatic HER2-ultralow (IHC 0 with membrane staining) breast cancer
4. Unresectable or metastatic non-small cell lung cancer (NSCLC)

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5. Locally advanced or metastatic HER2-positive (IHC 3+ or IHC 2+/ISH positive) gastric or gastroesophageal junction adenocarcinoma
6. Unresectable or metastatic HER2-positive (IHC 3+) solid tumor

AND ALL of the following:

1. **NO** disease progression or unacceptable toxicity
2. Prescriber agrees to monitor for signs and symptoms of interstitial lung disease (ILD)
3. Prescriber agrees to monitor complete blood counts prior to each dose and as clinically indicated
4. Prescriber agrees to assess left ventricular ejection fraction (LVEF) at regular intervals during treatment as clinically indicated
5. Females of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Enhertu and for 7 months after the last dose
6. Male patients with female partners of reproductive potential **only**: patient will be advised to use effective contraception during treatment with Enhertu and for 4 months after the last dose

Prior - Approval *Renewal* Limits

Same as above