

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Enhertu (fam-trastuzumab deruxtecan-nxki)

Override(s)	Approval Duration
Prior Authorization	1 year

Medications
Enhertu (fam-trastuzumab deruxtecan-nxki)

APPROVAL CRITERIA

Requests for Enhertu (fam-trastuzumab deruxtecan-nxki) may be approved if the following criteria are met:

- I. Individual has a diagnosis of unresectable or metastatic HER2-positive (HER2+) breast cancer (NCCN 1) confirmed by *one* of the following:
 - A. Immunohistochemistry (IHC) is 3 +;
 - OR**
 - B. In situ hybridization (ISH) positive;
- AND**
- II. Individual is using as monotherapy; **AND**
- III. Individual has had at least two or more prior anti-HER2 therapies in the metastatic phase of breast cancer;

Requests for Enhertu (fam-trastuzumab deruxtecan-nxki) may not be approved for the following:

- I. When the above criteria are not met and for all other indications; **OR**
- II. When Enhertu is used in combination with other targeted biologic agents or chemotherapy agents.

Market Applicability							
Market	DC	GA	KY	MD	NJ	NY	WA
Applicable	X	X	X	X	X	X	X

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2020. URL: <http://www.clinicalpharmacology.com>. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. <http://dailymed.nlm.nih.gov/dailymed/about.cfm>. Accessed: January 15, 2019.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2020; Updated periodically.
5. 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.
6. NCCN Clinical Practice Guidelines in Oncology™. © 2019 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: <http://www.nccn.org/index.asp>. Accessed on January 15, 2019.
 - a. Breast Cancer. V1.2020. Revised January 15, 2020.

This policy does not apply to health plans or member categories that do not have pharmacy benefits, nor does it apply to Medicare. Note that market specific restrictions or transition-of-care benefit limitations may apply.