

Pharmacy Policy

Enhertu

Policy Number: 9.706

Version Number: 2.0

Version Effective Date: 9/1/2021

Product Applicability **All Plan+ Products**

Well Sense Health Plan

New Hampshire Medicaid

Boston Medical Center HealthNet Plan

MassHealth - MCO

MassHealth - ACO

Qualified Health Plans/ConnectorCare/Employer Choice Direct

Senior Care Options

Note: Disclaimer and audit information is located at the end of this document.

Prior Authorization Policy

Products Affected:

- Enhertu (fam-trastuzumab deruxtecan-nxki)

The Plan may authorize coverage of the above products for members meeting the following criteria:

Covered Use	All FDA approved indications not otherwise excluded
Exclusion Criteria	None
Required Medical Information	<ol style="list-style-type: none"> 1. Diagnosis of unresectable or metastatic HER2-positive breast cancer; AND <ol style="list-style-type: none"> a. Trial and failure of treatment with a regimen including trastuzumab and pertuzumab AND treatment with a regimen including ado-trastuzumab emtansine; OR 2. Diagnosis of locally advanced or metastatic HER2-positive gastric or gastroesophageal junction (GEJ) adenocarcinoma; AND <ol style="list-style-type: none"> a. Trial and failure of a trastuzumab-based regimen; AND

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	3. Quantity being prescribed is consistent with dosing listed in manufacturer package labeling
Age Restriction	18 years and older
Prescriber Restriction	Prescribed by or in consultation with an oncologist
Coverage Duration	6 months
Other criteria	Reauthorization: 1. Clinical condition has improved or stabilized (decreased progression) without unacceptable treatment-related adverse events

Appendix A: Anti-HER2 Drugs

Herceptin (trastuzumab)
Herzuma (trastuzumab-pkrb)
Kadcyla (ado-trastuzumab emtansine)
Kanjinti (trastuzumab-anns)
Ogivri (trastuzumab-dkst)
Perjeta (pertuzumab)
Phesgo (pertuzumab, trastuzumab, and hyaluronidase-zzxf)
Trazimera (trastuzumab-qyyp)

Applicable Coding

Code	Description
J9358	Injection, fam-trastuzumab deruxtecan-nxki, 1 mg

Clinical Background Information and References

1. Enhertu (fam-trestuzumab deruxtecan-nxki) [prescribing information]. Basking Ridge, NJ: Daiichi Sankyo, Inc.; January 2021.

Original Approval Date	Original Effective Date	Policy Owner	Approved by
12/1/2020	1/1/2021	Pharmacy Services	Pharmacy & Therapeutics (P&T) Committee

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Policy Revisions History			
Review Date	Summary of Revisions	Revision Effective Date	Approved by
12/1/2020	9.204 Enhertu Policy retired, new policy created	1/1/2021	P&T Committee
5/13/2021	P&T annual review. Specified trial/ failure requirements for breast cancer. Added gastric cancer diagnosis. Updated reauthorization language. Added Herceptin biosimilars to appendix.	9/1/2021	P&T Committee

Next Review Date

5/2022

Other Applicable Policies

Reference to Applicable Laws and Regulations, If Any

Disclaimer Information

Medical Policies are the Plan’s guidelines for determining the medical necessity of certain services or supplies for purposes of determining coverage. These Policies may also describe when a service or supply is considered experimental or investigational, or cosmetic. In making coverage decisions, the Plan uses these guidelines and other Plan Policies, as well as the Member’s benefit document, and when appropriate, coordinates with the Member’s health care Providers to consider the individual Member’s health care needs.

Plan Policies are developed in accordance with applicable state and federal laws and regulations, and accrediting organization standards (including NCQA). Medical Policies are also developed, as appropriate, with consideration of the medical necessity definitions in various Plan products, review of current literature, consultation with practicing Providers in the Plan’s service area who are medical experts in the particular field, and adherence to FDA and other government agency policies. Applicable state or federal mandates, as well as the Member’s benefit document, take precedence over these guidelines. Policies are reviewed and updated on an annual basis, or more frequently as needed. Treating providers are solely responsible for the medical advice and treatment of Members.

The use of this Policy is neither a guarantee of payment nor a final prediction of how a specific claim(s) will be adjudicated. Reimbursement is based on many factors, including member eligibility and benefits on the date of service; medical necessity; utilization management guidelines (when applicable); coordination of benefits; adherence with applicable Plan policies and procedures; clinical coding criteria; claim editing logic; and the applicable Plan – Provider agreement.

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