



Step Therapy: Trastuzumab / HER2 Inhibitors

Herceptin (trastuzumab) IV J9355 and Herceptin Hylecta (trastuzumab/hyaluronidase-oysk) J9356, Kadcyla (ado-trastuzumab) J9354, Enhertu (Fam-Trastuzumab Deruxtecan-nxki) J9358, Phesgo (Pertuzumab/Trastuzumab/Hyaluronidase-zzxf) are non-preferred. The preferred products are Ontruzant (trastuzumab-dttb) Q5112, Herzuma (trastuzumab-pkrb) Q5113, Ogivri (trastuzumab-dkst) Q5114, Trazimera (trastuzumab-qyyp) Q5116, Kanjinti (trastuzumab-anns) Q5117

Prior Authorization Step Therapy Medicare Part B Request Form

Instructions: * Indicates required information – Form may be returned if required information is not provided. Please fax this request to the appropriate fax number listed at the bottom of the page.

<input type="checkbox"/>	Date Requested _____
	Requestor _____ Clinic name: _____ Phone _____ / Fax _____

MEMBER INFORMATION

*Name: _____ *ID#: _____ *DOB: _____

PRESCRIBER INFORMATION

*Name: _____ MD FNP DO NP PA *Phone: _____

*Address: _____ *Fax: _____

DISPENSING PROVIDER / ADMINISTRATION INFORMATION

*Name: _____ Phone: _____

*Address: _____ Fax: _____

PROCEDURE / PRODUCT INFORMATION

HCPC Code	Name of Drug <input type="checkbox"/> Self-administered	Dose (Wt: _____ kg Ht: _____)	Frequency	End Date if known

Chart notes attached. Other important information: _____

Diagnosis: ICD10: _____ Description: _____

Provider attests the diagnosis provided is an FDA-Approved indication for this drug

CLINICAL INFORMATION

New Start or Initial Request: (Clinical documentation required for all requests)

Provider has reviewed the attached “Criteria for Approval” and attests the member meets ALL required PA criteria.

If not, please provide clinical rationale for formulary exception: _____

Continuation Requests: (Clinical documentation required for all requests)

Provider has reviewed the attached “Criteria for Continuation” and attests the member meets ALL required PA Continuation criteria.

Patient had an adequate response or significant improvement while on this medication.

If not, please provide clinical rationale for continuing this medication: _____

ACKNOWLEDGEMENT

Request By (Signature Required): _____ Date: ____ / ____ / ____

Any person who knowingly files a request for authorization of coverage of a medical procedure or service with the intent to injure, defraud or deceive any insurance company by providing materially false information or conceals material information for the purpose of misleading, commits a fraudulent insurance act, which is a crime and subjects such person to criminal and civil penalties. THIS AUTHORIZATION IS NOT A GUARANTEE OF PAYMENT. PAYMENT IS BASED ON BENEFITS IN EFFECT AT THE TIME OF SERVICE, MEMBER ELIGIBILITY AND MEDICAL NECESSITY.

For questions or assistance, please contact Customer Service at 1-877-672-8620, daily, 8am – 8pm (PST) (TTY users should call 1-800-735-2900).

Prior Authorization Group – Antineoplastic: HER2 Inhibitor - Trastuzumab PA

Drug Name(s):

HERCEPTIN (trastuzumab) IV	HERCEPTIN HYLECTA (trastuzumab/hyaluronidase-oysk)
KADCYLA (ado-trastuzumab)	KANJINTI (trastuzumab-anns)
ONTRUZANT (trastuzumab-dttb)	HERZUMA (trastuzumab-pkrb)
TRAZIMERA (trastuzumab-qyyp)	ENHERTU (fam-trastuzumab deruxtecan-nxki)
OGIVRI (trastuzumab-dkst)	PHEGO (Pertuzumab/Trastuzumab/Hyaluronidase-zzxf)

Criteria for approval of Non-Formulary/Preferred Drug:

1. Prescribed for an approved FDA diagnosis (as listed below):
2. Member has tried and failed at least ONE of the formulary alternatives: **Ontruzant, Herzuma, Trazimera, Kanjinti, Ogivri** OR
 - There is clinical documentation stating formulary alternatives are contraindicated.
3. Drug is being used appropriately per MCG GUIDELINES, CMS recognized compendia, authoritative medical literature, evidence-based guidelines and/or accepted standards of medical practice.
4. Member does not have any clinically relevant contraindications, or CMS/Plan exclusions, to the requested drug.
 - If the member meets all these criteria, they may be approved by the Plan for the requested drug.
 - Quantity limits and Tiering will be determined by the Plan.

Exclusion Criteria:

N/A

Prescriber Restrictions:

N/A

Coverage Duration:

Non-Preferred: Approval will be for 6 months

Preferred: Approval will be for 12 months

FDA Indications:

Herceptin, Herceptin Hylecta,

- Breast cancer, Adjuvant, HER2 overexpression (Herceptin only)
- Esophagogastric cancer, Adenocarcinoma, metastatic, HER2 overexpression, initial treatment, in combination with cisplatin and capecitabine or 5-fluorouracil (Herceptin only)
- Gastric cancer, Adenocarcinoma, metastatic, HER2 overexpression, initial treatment, in combination with cisplatin and capecitabine or 5-fluorouracil (Herceptin only)
- Metastatic breast cancer, HER2 overexpression, first-line treatment in combination with paclitaxel
- Metastatic breast cancer, HER2 overexpression, monotherapy in patients who have received at least 1 prior chemotherapy regimen

Enhertu

- Metastatic breast cancer, Or unresectable, HER2-low (IHC1+ or IHC 2+/ISH-), in patients who have received prior chemotherapy in a metastatic setting, or developed disease recurrence during or within 6 months of completing adjuvant chemotherapy
- Metastatic breast cancer, Or unresectable disease, HER2-positive, in patients who have received a prior anti-HER2-based regimen either in the metastatic setting or in the neoadjuvant or adjuvant setting and have developed disease recurrence during or within 6 months of completing therapy

Part B Prior Authorization Step Therapy Guidelines

- Metastatic gastroesophageal adenocarcinoma, Locally advanced or metastatic HER2-positive disease following a prior trastuzumab-based regimen
- Gastric cancer, Locally advanced or metastatic HER2-positive disease following a prior trastuzumab-based regimen
- Non-small cell lung cancer, Unresectable or metastatic, previously treated, HER2 mutation-positive

Phesgo

- Breast cancer, Adjuvant, HER2-positive, early stage, at high risk of recurrence, in combination with chemotherapy
- Breast cancer, Neoadjuvant, HER2-positive, locally advanced, inflammatory, or early stage (either greater than 2 cm in diameter or node positive) as part of a complete treatment regimen in combination with chemotherapy
- Metastatic breast cancer, HER2-positive, in combination with docetaxel, in patients who have not received prior anti-HER2 therapy or chemotherapy for metastatic disease

Off-Label Uses:

- Breast cancer, Neoadjuvant, HER2 overexpression, in combination with chemotherapy
- Malignant meningitis
- Metastatic breast cancer, HER2 overexpression, hormone receptor positive, postmenopausal women, in combination with anastrozole
- Metastatic breast cancer, HER2 overexpression, in combination with chemotherapy

Step Therapy:

Kanjinti, Ontruzant, Herzuma, Trazimera, Ogivri

FDA Indications:

- Breast cancer, Adjuvant, HER2 overexpression
- Esophagogastric cancer, Adenocarcinoma, metastatic, HER2 overexpression; initial treatment in combination with cisplatin and capecitabine or 5-fluorouracil
- Gastric cancer, Adenocarcinoma, metastatic, HER2 overexpression; initial treatment in combination with cisplatin and capecitabine or 5-fluorouracil
- Metastatic breast cancer, HER2 overexpression, first-line treatment in combination with paclitaxel
- Metastatic breast cancer, HER2 overexpression, monotherapy in patients who have received at least 1 prior chemotherapy regimen

Off-Label Uses:

- Breast cancer, Neoadjuvant, HER2 overexpression, in combination with chemotherapy
- Malignant meningitis
- Metastatic breast cancer, HER2 overexpression, hormone receptor positive, postmenopausal women, in combination with anastrozole
- Metastatic breast cancer, HER2 overexpression, in combination with chemotherapy

Kadcyla (ado-trastuzumab)

FDA Indications:

- Early breast cancer, HER2-positive, adjuvant monotherapy in patients with residual disease after neoadjuvant taxane and trastuzumab-based treatment
- Metastatic breast cancer, HER2-positive, monotherapy in patients who have received at least one prior trastuzumab and/or taxane therapy

Off-Label Uses:

- Breast cancer, Advanced or metastatic, HER2-positive, first-line therapy
- Non-small cell lung cancer, Advanced disease, previously treated, HER2 mutation-positive



Age Restrictions:

Adults 18 years and older

Other Clinical Consideration:

Evaluate cardiac function prior to and during treatment. Discontinue Herceptin for cardiomyopathy.

Infusion reactions, Pulmonary toxicity: Discontinue Herceptin for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome.

Resources:

<https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidenceexpert.DoIntegratedSearch?navitem=headerLogout>
<https://www.micromedexsolutions.com/micromedex2/librarian/PFDefaultActionId/evidenceexpert.DoIntegratedSearch?navitem=headerLogout#>

https://careweb.careguidelines.com/ed24/ac/ac04_086.htm

https://www.micromedexsolutions.com/micromedex2/librarian/CS/F87B29/ND_PR/evidenceexpert/ND_P/evidenceexpert/DUPLICATIONSHIELDSYN/C/725CBA/ND_PG/evidenceexpert/ND_B/evidenceexpert/ND_AppProduct/evidenceexpert/ND_T/evidenceexpert/PFActionId/evidenceexpert.GoToDashboard?docId=932801&contentSetId=100&title=Fam-Trastuzumab+Deruxtecan-nxki&servicesTitle=Fam-Trastuzumab+Deruxtecan-nxki&brandName=Enhertu&UserMdxSearchTerm=enhertu&=null#

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