Step Therapy: Trastuzumab / HER2 Inhibitors

Herceptin (trastuzumab) IV J9355 and Herceptin Hylecta (trastuzumab/hyaluronidase-oysk) J9356, Kadycla (ado-trastuzumab) J9354, Enhertu (fam-trastuzumab) J9358 are non-preferred. The preferred products are Ontruzant (-dttb) Q5112, Herzuma (-pkrb) Q5113, Ogivri (-dkst) Q5114, Trazimera (-qyyp) Q5116, Kanjinti (-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.*

☐	**Standard Request– (72 Hours)**	☐	**Urgent Request** (standard time frame could place the member's life, health or ability in serious jeopardy)
	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	Dose (Wt: _____ kg Ht:_____)	Frequency	End Date if known

☐ **Self-administered** ☐ **Provider-administered** ☐ **Home Infusion**

☐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.

Prior Authorization Group – Antineoplastic: HER2 Inhibitor - Trastuzumab PA

Drug Name(s):

HERCEPTIN (trastuzumab) IV
KADCYLA (ado-trastuzumab)
ONTRUZANT (trastuzumab-dttb)
TRAZIMERA (trastuzumab-qyyp)
HERCEPTIN HYLECTA (trastuzumab/hyaluronidase-oysk)
KANJINTI (trastuzumab-anns)
HERZUMA (trastuzumab-pkrb)
OGIVRI (trastuzumab-dkst)

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** 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, Enhertu

- 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

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 (trastuzumab-anns)

FDA Indications:

- 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, Ogivri, Ontruzant, Herzuma, Trazimera,

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

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