



Herceptin, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera

CareFirst Prior Authorization Request

CVS Caremark administers the prescription benefit plan for the patient identified. This patient's benefit plan requires prior authorization for certain medications in order for the drug to be covered. To make an appropriate determination, providing the most accurate diagnosis for the use of the prescribed medication is necessary. **Please respond below and fax this form to CVS Caremark toll-free at 1-855-330-1720.** If you have questions regarding the prior authorization, please contact CVS Caremark at **1-888-877-0518**. For inquiries or questions related to the patient's eligibility, drug copay or medication delivery; please contact the Specialty Customer Care Team: CaremarkConnect® 1-800-237-2767.

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Patient's Name: _____ Date: _____
Patient's ID: _____ Patient's Date of Birth: _____
Physician's Name: _____
Specialty: _____ NPI#: _____
Physician Office Telephone: _____ Physician Office Fax: _____

Referring Provider Info: ☐ Same as Requesting Provider

Name: _____ NPI#: _____
Fax: _____ Phone: _____

Rendering Provider Info: ☐ Same as Referring Provider ☐ Same as Requesting Provider

Name: _____ NPI#: _____
Fax: _____ Phone: _____

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia, and/or evidence-based practice guidelines.

Required Demographic Information:

Patient Weight: _____ kg

Patient Height: _____ cm

Please indicate the place of service for the requested drug:

- | | | |
|--|---------------------------------|---|
| <input type="checkbox"/> Ambulatory Surgical | <input type="checkbox"/> Home | <input type="checkbox"/> Off Campus Outpatient Hospital |
| <input type="checkbox"/> On Campus Outpatient Hospital | <input type="checkbox"/> Office | <input type="checkbox"/> Pharmacy |

What is the ICD-10 code? _____

Send completed form to: Case Review Unit CVS Caremark Specialty Programs Fax: 1-855-330-1720

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Exception Criteria Questions:

A. What is the requested product?

- ☐ Kanjinti, *Skip to Clinical Criteria Questions*
- ☐ Ogivri, *Continue to Question B*
- ☐ Ontruzant, *Continue to Question B*
- ☐ Herceptin, *Continue to Question B*
- ☐ Herzuma, *Continue to Question B*
- ☐ Trazimera, *Skip to Clinical Criteria Questions*

B. The preferred products for your patient's health plan are Kanjinti and Trazimera.

Can the patient's treatment be switched to one of the preferred products?

- ☐ Yes, Kanjinti, *Skip to Clinical Criteria Questions*
- ☐ Yes, Trazimera, *Skip to Clinical Criteria Questions*
- ☐ No, *Continue to Question C*

C. Did the patient have a documented intolerable adverse event to both preferred products (Kanjinti and Trazimera)? **Action Required:** If 'Yes', attach supporting chart note(s)

- ☐ Yes, *Continue to Question D*
- ☐ No, *Continue to Question E*

D. Was the documented intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products)? **Action Required:** If 'Yes', attach supporting chart note(s)

- ☐ Yes, *Continue to Question E*
- ☐ No, *Skip to Clinical Criteria Questions*

E. Did the patient have a documented inadequate response to both preferred products (Kanjinti and Trazimera)? **Action Required:** If 'Yes', attach supporting chart note(s)

- ☐ Yes, *Skip to Clinical Criteria Questions*
- ☐ No, *Continue to Question F*

F. Does the patient have a contraindication to both preferred products (Kanjinti and Trazimera)? **Action Required:** If 'Yes', attach supporting chart note(s)

- ☐ Yes, *Continue to Clinical Criteria Questions*
- ☐ No, *Continue to Clinical Criteria Questions*

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Criteria Questions:

1. What is the patient's diagnosis?

- ☐ Breast cancer, *Continue to 2*
- ☐ Esophageal, gastric or esophagogastric junction cancer, *Continue to 2*
- ☐ Uterine serous carcinoma or carcinosarcoma, *Continue to 2*
- ☐ Salivary gland tumor, *Continue to 2*
- ☐ Colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, *Continue to 2*
- ☐ Biliary tract cancers, including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer, *Continue to 2*
- ☐ Other, please specify. _____, *Continue to 2*

2. Is the request for continuation of therapy with a trastuzumab product?

- ☐ Yes, *Continue to 3*
- ☐ No, *Continue to 6*

3. Is there evidence of unacceptable toxicity or disease progression while on the current regimen?

- ☐ Yes, *Continue to 4*
- ☐ No, *Continue to 4*

4. Is the requested drug being used as neoadjuvant or adjuvant treatment of breast cancer?

- ☐ Yes, *Continue to 5*
- ☐ No, *No Further Questions*

5. How many months has the patient received therapy with the requested drug?

_____ months, *No further questions*

6. What is the patient's diagnosis?

- ☐ Breast cancer, *Continue to 7*
- ☐ Esophageal, gastric or esophagogastric junction cancer, *Continue to 11*
- ☐ Uterine serous carcinoma or carcinosarcoma, *Continue to 14*
- ☐ Salivary gland tumor, *Continue to 17*
- ☐ Colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, *Continue to 20*
- ☐ Biliary tract cancers, including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer, *Continue to 26*

7. What is the human epidermal growth factor receptor 2 (HER2) status of the disease? **ACTION REQUIRED:**

Please attach chart note(s) or test results of human epidermal growth factor receptor 2 (HER2) status.

- ☐ HER2 positive **ACTION REQUIRED:** Submit supporting documentation, *Continue to 8*
- ☐ HER2 negative **ACTION REQUIRED:** Submit supporting documentation, *Continue to 8*
- ☐ Unknown, *Continue to 8*

8. In which clinical setting will the requested drug be used?

- ☐ Preoperative/neoadjuvant treatment, *Continue to 9*
- ☐ Adjuvant treatment, *Continue to 10*

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- ☐ Treatment of disease that has not responded to preoperative systemic therapy, recurrent, advanced unresectable, or metastatic disease (including brain metastases), *No further questions*
- ☐ Intra-cerebrospinal fluid (CSF) treatment for leptomeningeal metastases from breast cancer, *No further questions*
- ☐ Other, please specify. _____, *No further questions*

9. Will the requested drug be used as part of a complete treatment regimen?

- ☐ Yes, *Continue to 10*
- ☐ No, *Continue to 10*

10. How many months has the patient received therapy with the requested drug?

_____ months, *No further questions*

11. Will the requested drug be used for treatment or palliative therapy of esophageal, gastric, or esophagogastric junction cancer?

- ☐ Yes, *Continue to 12*
- ☐ No, *Continue to 12*

12. What is the human epidermal growth factor receptor 2 (HER2) status of the disease?

- ☐ HER2 positive **ACTION REQUIRED:** *Submit supporting documentation, Continue to 13*
- ☐ HER2 negative **ACTION REQUIRED:** *Submit supporting documentation, Continue to 13*
- ☐ Unknown, *Continue to 13*

13. Will the requested drug be used in combination with chemotherapy?

- ☐ Yes, *No Further Questions*
- ☐ No, *No Further Questions*

14. What is the human epidermal growth factor receptor 2 (HER2) status of the disease? **ACTION REQUIRED:** Please attach chart note(s) or test results of human growth factor receptor 2 (HER2) status.

- ☐ HER2 positive **ACTION REQUIRED:** *Submit supporting documentation, Continue to 15*
- ☐ HER2 negative **ACTION REQUIRED:** *Submit supporting documentation, Continue to 15*
- ☐ Unknown, *Continue to 15*

15. What is the clinical setting in which the requested drug will be used?

- ☐ Stage III-IV disease, *Continue to 16*
- ☐ Recurrent disease, *Continue to 16*
- ☐ Metastatic disease, *Continue to 16*
- ☐ Other, please specify. _____, *Continue to 16*

16. Will the requested drug be used in combination with carboplatin and paclitaxel?

- ☐ Yes, *No Further Questions*
- ☐ No, *No Further Questions*

17. What is the human epidermal growth factor receptor 2 (HER2) status of the disease? **ACTION REQUIRED:** Please attach chart note(s) or test results of human epidermal growth factor receptor 2 (HER2) status.

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- ☐ HER2 positive **ACTION REQUIRED:** Submit supporting documentation, Continue to 18
- ☐ HER2 negative **ACTION REQUIRED:** Submit supporting documentation, Continue to 18
- ☐ Unknown, Continue to 18

18. What is the clinical setting in which the requested drug will be used?

- ☐ Recurrent disease, Continue to 19
- ☐ Unresectable disease, Continue to 19
- ☐ Metastatic disease, Continue to 19
- ☐ Other, please specify. _____, Continue to 19

19. What is the requested regimen?

- ☐ As a single agent, No further questions
- ☐ In combination with docetaxel or pertuzumab (Perjeta), No further questions
- ☐ Other, please specify. _____, No further questions

20. What is the human epidermal growth factor receptor 2 (HER2) status of the disease? **ACTION REQUIRED:** Please attach chart note(s) or test results of human epidermal growth factor receptor 2 (HER2) status.

- ☐ HER2-positive/amplified **ACTION REQUIRED:** Submit supporting documentation, Continue to 21
- ☐ Other or Unknown, Continue to 21

21. Is the disease negative (wild-type) for RAS (KRAS and NRAS) and BRAF mutations? **ACTION REQUIRED:** If Yes, please attach chart note(s) or test results confirming negative (wild-type) RAS (KRAS and NRAS) and BRAF mutation status.

- ☐ Yes **ACTION REQUIRED:** Submit supporting documentation, Continue to 22
- ☐ No, Continue to 22
- ☐ Unknown, Continue to 22

22. Will the requested drug be used in combination with tucatinib (Tukysa), pertuzumab (Perjeta), or lapatinib (Tykerb)?

- ☐ Yes, Continue to 23
- ☐ No, Continue to 23

23. What is the clinical setting in which the requested drug will be used?

- ☐ Unresectable disease, Continue to 24
- ☐ Inoperable disease, Continue to 24
- ☐ Advanced disease, Continue to 24
- ☐ Metastatic disease, Continue to 24
- ☐ Other, please specify. _____, Continue to 24

24. Has the patient received prior therapy for the disease?

- ☐ Yes, No Further Questions
- ☐ No, Continue to 25

25. Is the patient appropriate for intensive therapy?

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- ☐ Yes, *No Further Questions*
☐ No, *No Further Questions*

26. What is the human epidermal growth factor receptor 2 (HER2) status of the disease? **ACTION REQUIRED:** Please attach chart note(s) or test results of human epidermal growth factor receptor 2 (HER2) status.

- ☐ HER2 positive **ACTION REQUIRED:** *Submit supporting documentation, Continue to 27*
☐ HER2 negative **ACTION REQUIRED:** *Submit supporting documentation, Continue to 27*
☐ Unknown, *Continue to 27*

27. What is the clinical setting in which the requested drug will be used?

- ☐ Unresectable disease, *Continue to 28*
☐ Resected gross residual disease, *Continue to 28*
☐ Metastatic disease, *Continue to 28*
☐ Other, please specify. _____, *Continue to 28*

28. What is the place in therapy in which the requested drug will be used?

- ☐ First-line treatment, *Continue to 29*
☐ Subsequent treatment, *Continue to 29*

29. What is the requested regimen?

- ☐ In combination with pertuzumab (Perjeta), *No further questions*
☐ In combination with tucatinib (Tukysa), *No further questions*
☐ Other, please specify. _____, *No further questions*

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| | | |
|---|---------------|----|
| Step Therapy Override: Complete if Applicable for the state of Maryland. | Please Circle | |
| Is the requested drug being used to treat stage four advanced metastatic cancer? | Yes | No |
| Is the requested drug's use consistent with the FDA-approved indication or the National Comprehensive Cancer Network Drugs & Biologics Compendium indication for the treatment of stage four advanced metastatic cancer and is supported by peer-reviewed medical literature? | Yes | No |
| Is the requested drug being used for an FDA-approved indication OR an indication supported in the compendia of current literature (examples: AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? | Yes | No |
| Does the prescribed quantity fall within the manufacturer's published dosing guidelines or within dosing guidelines found in the compendia of current literature (examples: package insert, AHFS, Lexicomp, Clinical Pharmacology, Micromedex, current accepted guidelines)? | Yes | No |
| Do patient chart notes document the requested drug was ordered with a paid claim at the pharmacy, the pharmacy filled the prescription and delivered to the patient or other documentation that the requested drug was prescribed for the patient in the last 180 days? | Yes | No |
| Has the prescriber provided proof documented in the patient chart notes that in their opinion the requested drug is effective for the patient's condition? | Yes | No |

| | | |
|---|---------------|----|
| Step Therapy Override: Complete if Applicable for the state of Virginia. | Please Circle | |
| Is the requested drug being used for an FDA-approved indication or an indication supported in the compendia of current literature (examples: AHFS, Micromedex, current accepted guidelines)? | Yes | No |
| Does the prescribed dose and quantity fall within the FDA-approved labeling or within dosing guidelines found in the compendia of current literature? | Yes | No |
| Is the request for a brand drug that has an AB-rated generic equivalent or interchangeable biological product available? | Yes | No |
| Has the patient had a trial and failure of the AB-rated generic equivalent or interchangeable biological product due to an adverse event (examples: rash, nausea, vomiting, anaphylaxis) that is thought to be due to an inactive ingredient? | Yes | No |
| Is the preferred drug contraindicated? | Yes | No |
| Is the preferred drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen? | Yes | No |
| Has the patient tried the preferred drug while on their current or previous health benefit plan and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? | Yes | No |
| Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition? | Yes | No |

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by CVS Caremark or the benefit plan sponsor.

X _____

Prescriber or Authorized Signature

Date (mm/dd/yy)

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