



Herceptin [trastuzumab] and biosimilars

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 copy 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:

- Ambulatory Surgical Home Off Campus Outpatient Hospital
 On Campus Outpatient Hospital Office Pharmacy

What is the requested drug?

- Herceptin Kanjinti Ogivri Trazimera Herzuma Ontruzant Hercessi

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, *Skip to Clinical Criteria Questions*
- Trazimera, *Skip to Clinical Criteria Questions*
- Herceptin, *Continue to Question B*
- Herceptin Hylecta, *Please obtain Form for preferred product and submit for corresponding PA*
- Hercessi, *Continue to Question B*
- Herzuma, *Continue to Question B*
- Ontruzant, *Continue to Question B*

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

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

- Yes, Kanjinti, *Skip to Clinical Criteria Questions*
- Yes, Ogivri, *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 all of the preferred products (Kanjinti, Ogivri, 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 'No', 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 all of the preferred products (Kanjinti, Ogivri, 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 all of the preferred products (Kanjinti, Ogivri, 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?
 - Anal adenocarcinoma, *Continue to 2*
 - Appendiceal neoplasms and cancers (including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified), *Continue to 2*
 - Biliary tract cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer), *Continue to 2*
 - Breast cancer, *Continue to 2*
 - Colon cancer, *Continue to 2*
 - Esophageal, gastric or esophagogastric junction cancer, *Continue to 2*
 - Rectal cancer, *Continue to 2*
 - Salivary gland tumor, *Continue to 2*
 - Small bowel adenocarcinoma, *Continue to 2*
 - Uterine serous carcinoma or carcinosarcoma, *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 7*

3. Is there evidence of unacceptable toxicity while on the current regimen?
 - Yes, *Continue to 4*
 - No, *Continue to 4*

4. Is there evidence of disease progression while on the current regimen?
 - Yes, *Continue to 5*
 - No, *Continue to 5*

5. Is the requested drug being used as neoadjuvant or adjuvant treatment of breast cancer?
 - Yes, *Continue to 6*
 - No, *No Further Questions*

6. How many months has the patient received therapy with a trastuzumab product?
_____ month(s), *No further questions*

7. What is the patient's diagnosis?
 - Anal adenocarcinoma, *Continue to 41*
 - Appendiceal neoplasms and cancers (including appendiceal adenocarcinoma, goblet cell adenocarcinoma, and undifferentiated carcinoma not otherwise specified), *Continue to 25*
 - Biliary tract cancers (including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer), *Continue to 31*
 - Breast cancer, *Continue to 8*
 - Colon cancer, *Continue to 41*
 - Esophageal, gastric or esophagogastric junction cancer, *Continue to 16*
 - Rectal cancer, *Continue to 41*
 - Salivary gland tumor, *Continue to 22*
 - Small bowel adenocarcinoma, *Continue to 35*
 - Uterine serous carcinoma or carcinosarcoma, *Continue to 19*

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8. 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 12
- HER2 negative **ACTION REQUIRED:** Submit supporting documentation, Continue to 9
- Unknown, No further questions

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

- Metastatic disease, Continue to 10
- Other, please specify. _____, Continue to 10

10. What is the requested regimen?

- The requested drug in combination with neratinib and fulvestrant, Continue to 11
- The requested drug in combination with tucatinib with or without fulvestrant, Continue to 11
- Other, please specify. _____, Continue to 11

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

- Third-line or later therapy, No further questions
- Other, please specify, _____, No further questions

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

- Preoperative/neoadjuvant treatment, Continue to 13
- Adjuvant treatment, Continue to 15
- 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

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

- Yes, Continue to 14
- No, Continue to 14

14. Has the patient previously been treated with the requested drug as neoadjuvant or adjuvant therapy?

- Yes, Continue to 15
- No, No Further Questions

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

_____ month(s), No further questions

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

- Yes, Continue to 17
- No, Continue to 17

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.

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

- Yes, No Further Questions

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No, *No Further Questions*

19. 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 20*
 HER2 negative (**ACTION REQUIRED:** *Submit supporting documentation, Continue to 20*)
 Unknown, *Continue to 20*

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

- Stage III-IV disease, *Continue to 21*
 Recurrent disease, *Continue to 21*
 Metastatic disease, *Continue to 21*
 Other, please specify. _____, *Continue to 21*

21. Will the requested drug be used in combination with carboplatin and paclitaxel and continued as a single agent for maintenance therapy?

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

22. 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 23*
 HER2 negative **ACTION REQUIRED:** *Submit supporting documentation, Continue to 23*
 Unknown, *Continue to 23*

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

- Recurrent disease, *Continue to 24*
 Unresectable disease, *Continue to 24*
 Metastatic disease, *Continue to 24*
 Other, please specify. _____, *Continue to 24*

24. 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*

25. 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 26*
 HER2 negative **ACTION REQUIRED:** *Submit supporting documentation, Continue to 26*
 Unknown, *Continue to 26*

26. 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 27*
 No, *Continue to 27*
 Unknown, *Continue to 27*

27. Has the patient been previously treated with a HER2 inhibitor?

- Yes, *Continue to 28*

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No, *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. Will the requested drug be used in combination with pertuzumab (Perjeta) or tucatinib (Tukysa)?

- Yes, *No Further Questions*
 No, *Continue to 30*

30. Will the requested drug be used to treat appendiceal adenocarcinoma?

- Yes, *Continue to 41*
 No, *Continue to 41*

31. Does the patient have human epidermal growth factor receptor 2 (HER2) (IHC 3+/ISH +/NGS amplification) disease? **ACTION REQUIRED:** If Yes, attach chart note(s) or test results of human epidermal growth factor receptor 2 (HER2) status.

- Yes **ACTION REQUIRED:** *Submit supporting documentation, Continue to 32*
 No, *Continue to 32*
 Unknown, *Continue to 32*

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

- Unresectable disease, *Continue to 33*
 Resected gross residual (R2) disease, *Continue to 33*
 Metastatic disease, *Continue to 33*
 Other, please specify. _____, *Continue to 33*

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

- First-line treatment, *Continue to 34*
 Subsequent treatment, *Continue to 34*

34. 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*

35. 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 amplified **ACTION REQUIRED:** *Submit supporting documentation, Continue to 36*
 Other or unknown, *Continue to 36*

36. 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 37*
 No, *Continue to 37*
 Unknown, *Continue to 37*

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

- First-line treatment, *Continue to 38*
 Subsequent treatment, *Continue to 38*

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

- Advanced disease, *Continue to 39*
- Metastatic disease, *Continue to 39*
- Other, please specify. _____, *Continue to 39*

39. Has the patient been previously treated with a HER2 inhibitor?

- Yes, *Continue to 40*
- No, *Continue to 40*

40. Will the requested drug be used in combination with pertuzumab (Perjeta) or tucatinib (Tukysa)?

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

41. 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 42*
- Other or Unknown, *Continue to 42*

42. 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 43*
- No, *Continue to 43*
- Unknown, *Continue to 43*

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

- Yes, *Continue to 44*
- No, *Continue to 44*

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

- Unresectable disease, *Continue to 45*
- Advanced disease, *Continue to 45*
- Metastatic disease, *Continue to 45*
- Other, please specify. _____, *Continue to 45*

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

- Yes, *No Further Questions*
- No, *Continue to 46*

46. Is the patient appropriate for intensive therapy?

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

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Step Therapy Override 2197-D: Complete if Applicable for the state of Maryland.	Please Circle	
1. 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
2. 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
3. Is the alternate drug FDA-approved for the medical condition being treated? <i>If No, No Further Questions</i>	Yes	No
4. Has the prescriber documented in the patient's chart that the requested drug was ordered for the patient in the past 180 days? <i>If No, Skip to 6</i>	Yes	No
5. Has the prescriber documented in the patient's chart that in their opinion the requested drug is effective for the patient's condition? <i>If Yes or No, No Further Questions</i>	Yes	No
6. Is the alternate drug contraindicated or will likely cause an adverse reaction to the patient? <i>If Yes, No Further Questions</i>	Yes	No
7. Is the alternate drug expected to be ineffective based on the known clinical characteristics of the patient and the known characteristics of the prescription drug regimen? <i>If Yes, No Further Questions</i>	Yes	No
8. Is the patient stable on the requested drug for the medical condition under consideration? <i>If Yes, No Further Questions</i>	Yes	No
9. Has the patient tried a prescription drug while covered under their current policy or a previous source of coverage, that is in the same pharmacologic class or has the same mechanism of action as the alternate drug and it was discontinued due to lack of efficacy or effectiveness, diminished effect, or an adverse event? <i>No Further Questions</i>	Yes	No

Step Therapy Override 3145-D: Complete if Applicable for the state of Virginia.	Please Circle	
1. 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
2. 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
3. Is the alternate drug contraindicated? <i>If Yes, No Further Questions</i>	Yes	No
4. Is the alternate drug expected to be ineffective based on the known clinical characteristics of the patient and the prescription drug regimen? <i>If Yes, No Further Questions</i>	Yes	No
5. Has the patient tried the alternate 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? NOTE: Pharmaceutical drug samples are not considered trial and failure of a preferred drug. <i>If Yes, No Further Questions</i>	Yes	No
6. Is the patient currently receiving a positive therapeutic outcome with the requested drug for their medical condition? <i>No Further Questions</i>	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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