Herceptin [trastuzumab] and biosimilars

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.

The recipient of this fax may make a request to opt-out of receiving telemarketing fax transmissions from CVS Caremark. There are numerous ways you may opt-out: The recipient may call the toll-free number at 877-265-2711, at any time, 24 hours a day/7 days a week. The recipient may also send an opt-out request via email to do_not_call@cvscaremark.com. An opt out request is only valid if it (1) identifies the number to which the request relates, and (2) if the person/entity making the request does not, subsequent to the request, provide express invitation or permission to CVS Caremark to send facsimile advertisements to such person/entity at that particular number. CVS Caremark is required by law to honor an opt-out request within thirty days of receipt.

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*

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

Exception Criteria Questions:

A. What drug is being prescribed?
- ❑ Herceptin
- ❑ Kanjinti, *Skip to Clinical Criteria Questions*
- ❑ Ogivri, *Skip to Clinical Criteria Questions*
- ❑ Herzuma, *Skip to Clinical Criteria Questions*
- ❑ Ontruzant, *Skip to Clinical Criteria Questions*
- ❑ Trazimera, *Skip to Clinical Criteria Questions*

B. Is the product being requested for the treatment of one of the following indications?
- HER2-overexpressing breast cancer
- HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma

❑ Yes ❑ No *If No, Skip to Clinical Criteria Questions*

C. The preferred products for your patient's health plan are Herzuma, Kanjinti, Ogivri, Ontruzant and Trazimera. Can the patient's treatment be switched to any of the preferred products?
- ❑ Yes – Herzuma, *Skip to Clinical Criteria Questions*
- ❑ Yes – Kanjinti, *Skip to Clinical Criteria Questions*
- ❑ Yes – Ogivri, *Skip to Clinical Criteria Questions*
- ❑ Yes – Ontruzant, *Skip to Clinical Criteria Questions*
- ❑ Yes – Trazimera, *Skip to Clinical Criteria Questions*
- ❑ No

D. Does the patient have a documented intolerable adverse event to at least three of the preferred products (Herzuma, Kanjinti, Ogivri, Ontruzant, or Trazimera)? ***Action Required: If 'Yes', attach supporting chart note(s).***
❑ Yes ❑ No

E. Was the documented intolerable adverse event an expected adverse event attributed to the active ingredient as described in the prescribing information? ***Action Required: If 'No', attach supporting chart note(s).***
❑ Yes ❑ No

Clinical Criteria Questions:

1. What is the prescribed drug? ❑ Herceptin ❑ Kanjinti ❑ Ogivri ❑ Trazimera ❑ Herzuma ❑ Ontruzant

2. What is the patient's diagnosis?
   - ❑ Breast cancer
   - ❑ Esophageal, gastric or gastroesophageal junction cancer
   - ❑ Uterine serous carcinoma
   - ❑ Salivary gland tumor
   - ❑ Colorectal cancer
   - ❑ Other _____

3. What is the ICD-10 code? _____

4. Is the request for continuation of therapy with a trastuzumab product? ❑ Yes ❑ No *If No, skip to #9*

5. Is there evidence of unacceptable toxicity or disease progression while on the current regimen? ❑ Yes ❑ No

6. Is the requested drug being used as neoadjuvant or adjuvant treatment of breast cancer?
   ❑ Yes ❑ No *If No, no further questions*

7. How many months of trastuzumab therapy has the patient received? _____ months

8. Has the patient received the requested drug for 12 months (52 weeks) or greater?
   ❑ Yes ❑ No *No further questions*

9. What is the human epidermal growth factor receptor 2 (HER2) status of the disease? ***ACTION REQUIRED: Please attach documentation of human epidermal growth factor receptor 2 (HER2) status.***
   ❑ HER2 positive ❑ HER2 negative ❑ HER2 amplified ❑ Unknown

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Complete the following section based on the patient's diagnosis, if applicable.

Section A: Breast Cancer

10. In which clinical setting will the requested drug be used?
    - ❑ Preoperative/neoadjuvant treatment
    - ❑ Adjuvant treatment, *skip to #12*
    - ❑ Treatment of 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 _____

11. Will the requested drug be used as part of a complete treatment regimen? ❑ Yes ❑ No

12. How many months of trastuzumab therapy has the patient received? _____ months

Section B: Esophageal, Gastric, or Gastroesophageal Junction Cancer

13. Will the requested drug be used in combination with chemotherapy? ❑ Yes ❑ No

Section C: Uterine Serous Carcinoma

14. Does the patient have advanced or recurrent disease?
    - ❑ Advanced disease
    - ❑ Recurrent disease
    - ❑ None of the above

15. Will the requested drug be used in combination with carboplatin and paclitaxel? ❑ Yes ❑ No

Section E: Colorectal Cancer

16. Does the patient have RAS and BRAF wild-type disease? ***ACTION REQUIRED: Please attach documentation of RAS and BRAF mutation status.*** ❑ Yes ❑ No ❑ Unknown

17. Will the requested drug be used in combination with pertuzumab or lapatinib? ❑ Yes ❑ No

18. Will the requested drug be used as subsequent therapy for progression of advanced or metastatic disease? *If Yes, no further questions* ❑ Yes ❑ No

19. Is the patient appropriate for intensive therapy? ❑ Yes ❑ No

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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