Herceptin [trastuzumab] and biosimilars

Prior Authorization Request

Your patient's benefit plan requires prior authorization for certain medications. In order to make appropriate medical necessity determinations, your patient's diagnosis and other clinical information is required. **Please complete the information requested on the form below and fax this form along with supporting clinical documentation to Priority Partners, toll-free at 1-866-212-4756 to initiate the review process.** If you have questions regarding the prior authorization please contact Priority Partners at 888-819-1043 Option 4.

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*

Drug Information:

Strength/Measure _____ *Units* ❑ ml ❑ Gm ❑ mg ❑ ea. ❑ Un
Directions(sig) _____ *Route of administration* _____
Dosing frequency _____

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*

Send completed form to: Priority Partners Fax: 1-866-212-4756

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B. 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

C. 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

D. 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 patient's diagnosis?

❒ Breast cancer (If checked, go to 2)

❒ Esophageal, gastric or gastroesophageal junction cancer (If checked, go to 2)

❒ Uterine serous carcinoma (If checked, go to 2)

❒ Salivary gland tumor (If checked, go to 2)

❒ Colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma (If checked, go to 2)

❒ Hepatobiliary cancers, including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer (If checked, go to 2)

❒ Other, please specify. _____ (If checked, go to 2)

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

❒ Yes (If checked, go to 3)

❒ No (If checked, go to 6)

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

❒ Yes (If checked, go to 4)

❒ No (If checked, go to 4)

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

❒ Yes (If checked, go to 5)

❒ No (If checked, *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 (If checked, go to 7)

❒ Esophageal, gastric or gastroesophageal junction cancer (If checked, go to 11)

❒ Uterine serous carcinoma (If checked, go to 14)

❒ Salivary gland tumor (If checked, go to 17)

❒ Colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma (If checked, go to 18)
❒ Hepatobiliary cancers, including intrahepatic and extrahepatic cholangiocarcinoma and gallbladder cancer (If checked, go to 24)

7. What is the human epidermal growth factory 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 (If checked, go to 8)

❒ HER2 negative ***ACTION REQUIRED***: Submit supporting documentation (If checked, go to 8)
❒ Unknown (If checked, go to 8)

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

❒ Preoperative/neoadjuvant treatment (If checked, go to 9)

❒ Adjuvant treatment (If checked, go to 10)
❒ Treatment of disease that has not responded to preoperative systemic therapy, recurrent, advanced unresectable, or metastatic disease (including brain metastases) (If checked, *no further questions*)
❒ Intra-cerebrospinal fluid (CSF) treatment for leptomeningeal metastases from breast cancer (If checked, *no further questions*)
❒ Other, please specify. _____ (If checked, *no further questions*)

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

❒ Yes (If checked, go to 10)

❒ No (If checked, go 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 gastroesophageal junction cancer?

❒ Yes (If checked, go to 12)

❒ No (If checked, go to 12)

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

❒ HER2 positive ***ACTION REQUIRED***: Submit supporting documentation (If checked, go to 13)

❒ HER2 negative ***ACTION REQUIRED***: Submit supporting documentation (If checked, go to 13)
❒ Unknown (If checked, go to 13)

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

❒ Yes (If checked, *no further questions*)

❒ No (If checked, *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 (If checked, go to 15)

❒ HER2 negative ***ACTION REQUIRED***: Submit supporting documentation (If checked, go to 15

❒ Unknown (If checked, go to 15)

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

❒ Advanced disease (If checked, go to 16)

❒ Recurrent disease (If checked, go to 16)

❒ Metastatic disease (If checked, go to 16)

❒ Other, please specify. _____ (If checked, go to 16)

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

❒ Yes (If checked, *no further questions*)

❒ No (If checked, *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.

❒ HER2 positive ***ACTION REQUIRED***: Submit supporting documentation (If checked, *no further questions*)

❒ HER2 negative ***ACTION REQUIRED***: Submit supporting documentation (If checked, *no further questions*)

❒ Unknown (If checked, *no further questions*)

18. 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 (If checked, go to 19)

❒ Other or Unknown (If checked, go to 19)

19. Is the disease negative (wild-type) for RAS (KRAS and NRAS) and BRAF mutations? ***ACTION REQUIRED***: 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 (If checked, go to 20)

❒ No ***ACTION REQUIRED***: Submit supporting documentation (If checked, go to 20)

❒ Unknown (If checked, go to 20)

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

❒ Yes (If checked, go to 21)

❒ No (If checked, go to 21)

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

❒ Unresectable disease (If checked, go to 22)

❒ Advanced disease (If checked, go to 22)

❒ Metastatic disease (If checked, go to 22)

❒ Other, please specify. _____ (If checked, go to 22)

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

❒ Yes (If checked, *no further questions*)

❒ No (If checked, Go to 23)

23. Is the patient appropriate for intensive therapy?

❒ Yes (If checked, *no further questions*)

❒ No (If checked, *no further questions*)

24. 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 (If checked, go to 25)

❒ HER2 negative ***ACTION REQUIRED***: Submit supporting documentation (If checked, go to 25)

❒ Unknown (If checked, go to 25)

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

❒ Unresectable disease (If checked, go to 26)

❒ Metastatic disease (If checked, go to 26)

❒ Other, please specify. _____ (If checked, go to 26)

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

❒ First-line treatment (If checked, go to 27)

❒ Subsequent treatment (If checked, go to 27)

27. Will the requested drug be used in combination with pertuzumab (Perjeta)?

❒ Yes (If checked, *no further questions*)

❒ No (If checked, *no further questions*)

I attest that this information is accurate and true, and that documentation supporting this information is available for review if requested by Priority Partners.

X_____

Prescriber or Authorized Signature **Date (mm/dd/yy)**

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