



Your *greater* Minnesota health plan

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PrimeWest Health Part B Step Therapy Criteria for Trastuzumab

Effective 1/1/23

Reviewed 2/2023

I. Initial criteria

Herceptin or Herceptin Hylecta will be approved when ALL of the following are met:

1. The requested medication is being used for ONE of the following:
 - a. An FDA-approved indication
OR
 - b. An indication in CMS-approved compendia
AND
If OGIVRI (subcutaneous), why IV biosimilar cannot be used
AND
2. ONE of the following:
 - a. Information has been provided that indicates the patient has been treated with the requested medication in the past 365 days
OR
 - b. There is documentation that the patient has had an ineffective treatment response to the active ingredient(s) of two preferred medications (Herzuma, Ontruzant, Kanjinti, and Trazimera)
OR
 - c. The patient has a documented intolerance, hypersensitivity, or FDA labeled contraindication to the active ingredient(s) of ALL preferred medications
OR
 - d. The prescriber has submitted documentation indicating ALL preferred medications are likely to be ineffective or are likely to cause an adverse reaction or other harm to the patient
OR
 - e. BOTH of the following:
 - i. NCCN does NOT specify the preferred medications as a preferred regimen for the requested indication
AND
 - ii. NCCN specifies the requested medication as a preferred regimen for the requested indication

Length of Approval: up to 12 months

NOTES:

- Coverage of one Medicare Part B Step Therapy medication could equate to multiple medication authorizations when they share the same Medicare Part B Step Therapy criteria.
- LCD/NCD criteria review completed, if applicable, in addition to the Plan's Medicare Part B Step Therapy criteria.



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II. References

1. Micromedex (electronic version), IBM Watson Health information, URL address (<https://www.micromedexsolutions.com/>) date accessed 02/2023.
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3. Ogivri [package insert]. Morgantown, WV; Mylan Pharmaceuticals, Inc.; February 2021. Accessed February 2023.
4. Kanjinti [package insert]. Thousand Oaks, CA; Amgen, Inc.; October 2022. Accessed February 2023.
5. Trazimera [package insert]. Cork, Ireland; Pfizer Ireland Pharmaceuticals; November 2020. Accessed February 2023.
6. Herzuma [package insert]. Yeonsu-gu, Incheon, Republic of Korea; Celltrion, Inc.; May 2019. Accessed February 2023.
7. Ontruzant [package insert]. Yeonsu-gu, Incheon, Republic of Korea; Samsung Bioepsis Co., Ltd.; June 2021. Accessed February 2023.
8. CMS Memorandum titled Prior Authorization and Step Therapy for Part B Drugs in Medicare Advantage, dated August 7, 2018; see: https://www.cms.gov/Medicare/Health-Plans/HealthPlansGenInfo/Downloads/MA_Step_Therapy_HPMS_Memo_8_7_2018.pdf