Herceptin (trastuzumab) and biosimilars

Policy Number: 5.02.536
Last Review: 03/2021
Origination: 03/2017
Next Review: 03/2022

Policy
Blue Cross and Blue Shield of Kansas City (Blue KC) will provide coverage for Herceptin and any biosimilars when it is determined to be medically necessary because the following criteria have been met.

- Herceptin (trastuzumab intravenous infusion - Genentech)
- Herceptin Hylecta (trastuzumab and hyaluronidase Injection – Genentech)
- Kanjinti (trastuzumab-anns injection for intravenous infusion – Amgen)
- Ogivri (trastuzumab-dkst injection for intravenous infusion – Mylan)
- Trazimera (trastuzumab-qyyp injection for intravenous infusion – Pfizer)
- Herzuma (trastuzumab-pkrb injection for intravenous infusion – Teva)
- Ontruzant (trastuzumab-dttb injection for intravenous infusion – Merck)

When Policy Topic is covered
Kanjinti, Ogivri, and Trazimera are the co-preferred trastuzumab biosimilar agents. Members must try one preferred biosimilar before coverage of non-preferred Herceptin, Herceptin Hylecta or another non-preferred trastuzumab biosimilar (Herzuma, or Ontruzant) when requested for an indication for which the biosimilar has been FDA-approved OR is supported by NCCN Guidelines® or NCCN Compendium® with a recommendation of category level 1 or 2A.

1. Trastuzumab is considered medically necessary for the treatment (adjuvant) of human epidermal growth receptor 2 (HER2)-overexpressing node positive or node negative (estrogen receptor/progesterone receptor negative or with 1 high-risk feature) breast cancer as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; as part of a treatment regimen with docetaxel and carboplatin; or as a single agent following multimodality anthracycline-based therapy.

2. Trastuzumab is considered medically necessary for the first-line treatment of HER2-overexpressing metastatic breast cancer (in combination with paclitaxel); single-agent treatment of HER2-overexpressing breast cancer in patients who have received 1 or more chemotherapy regimens for metastatic disease.

3. Trastuzumab is considered medically necessary for the Treatment of HER2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (in combination with cisplatin and either capecitabine or 5-fluorouracil) in patients who have not received prior treatment for metastatic disease.

DOSING:
Adult FDA-approved uses:
See FDA labeling
Pediatric FDA-approved uses:
Safety and effectiveness have not been established. No pediatric dosing information is available.

Drug must be sourced from an approved specialty infusion provider.

When Policy Topic is not covered
Trastuzumab may be considered investigational in patients under age 18 or in patients who do not meet the criteria for medical necessity.

Considerations
Trastuzumab requires prior authorization through the Clinical Pharmacy Department.

This Blue Cross and Blue Shield of Kansas City policy Statement was developed using available resources such as, but not limited to: Food and Drug Administration (FDA) approvals, Facts and Comparisons, National specialty guidelines, Local medical policies of other health plans, Medicare (CMS), Local providers.

Description of Procedure or Service

Background
Herceptin (trastuzumab) is a monoclonal antibody that selectively binds with high affinity to the Human Epidermal Growth Factor Receptor – 2 (HER2) protein. Trastuzumab is a mediator of antibody-dependent cellular cytotoxicity (ADCC). Trastuzumab's effects have been shown to be preferentially exerted on HER2-overexpressing cancer cells compared with cancer cells that do not over-express HER2 (1).

Regulatory Status
FDA-approved indication: Herceptin indicated for the adjuvant treatment of HER 2-overexpressing breast cancer and the treatment of HER 2-overexpressing metastatic gastric or gastroesophageal junction adenocarcinoma (1).

Herceptin carries a boxed warning regarding possible risks for cardiomyopathy, infusion reactions, pulmonary toxicity, and embryo-fetal toxicity. Trastuzumab use can result in cardiac failure that manifests as congestive heart failure (CHF) or decreased left ventricular ejection fraction (LVEF), with greatest risk when administered concurrently with anthracyclines (1).

Exposure to Herceptin during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death (1).

Safety and effectiveness in pediatric patients have not been established (1).

Rationale
Herceptin (trastuzumab) is a monoclonal antibody that selectively binds with high affinity to the HER2 protein. Trastuzumab is a mediator of antibody-dependent cellular cytotoxicity (ADCC). Trastuzumab’s effects have been shown to be preferentially exerted on HER2-overexpressing cancer cells compared with cancer cells that do not overexpress HER2 (1).

Prior approval is required to ensure the safe, clinically appropriate and cost-effective use of Herceptin while maintaining optimal therapeutic outcomes.

References
1. Herceptin (trastuzumab) [prescribing information]. South San Francisco, CA: Genentech Inc; February 2021.


24. Herzuma (trastuzumab-pkrb) [prescribing information]. North Wales, PA: Teva Pharmaceuticals USA Inc; May 2019.


Billing Coding/Physician Documentation Information

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Additional Policy Key Words
5.02.536

Policy Implementation/Update Information

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<th>Date</th>
<th>Description</th>
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<td>03/2017</td>
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<td>01/2020</td>
<td>Changed policy name to Herceptin (trastuzumab) and biosimilars; added biosimilars Kanjinti and Ogivri</td>
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<tr>
<td>03/2020</td>
<td>Updated wording for indications and added biosimilars Herzuma and Trazimera</td>
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<td>10/2020</td>
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<tr>
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