

MEDICAL REVIEW GUIDELINE

Trastuzumab Preferred Product Policy



Trastuzumab (Herceptin, Kanjinti, Ogivri, Ontruzant, Herzuma, Trazimera)

Effective Date: 01/01/2025

Medical Care Management Committee Approval: 8/15/2024

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Coverage Policy

This Medical Review Guideline (Guideline) is provided for informational purposes only and does not constitute medical advice. It is intended solely for the use of Community Health Choice, Inc. (Community) clinical staff as a guideline for use in determining medical necessity of requested procedures, medications and therapy. This Guideline does not address eligibility or benefit coverage. Other Policies and Coverage Determination Guidelines may apply. All reviewers must first identify enrollee eligibility, any federal or state regulatory requirements and the plan benefit coverage prior to use of this Medical Review Guideline. If there is a discrepancy between this Guideline and a member's benefit plan, summary plan description or contract, the benefit plan, summary plan description or contract will govern. Community reserves the right, in its sole discretion, to modify its Policies and Guidelines as necessary.

This policy applies to all trastuzumab products including, but not limited to the following*:

HCPCS Code	Description	Maximum Dosage per Administration
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg	8 mg/kg
Q5117	Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg	8 mg/kg
Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg	8 mg/kg
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg	8 mg/kg
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg	8 mg/kg
Q5116	Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg	8 mg/kg

*Any U.S. FDA-approved and launched trastuzumab biosimilar product not listed by name in this policy will be considered non-preferred until reviewed by Community

Preferred Product Criteria

Trazimera is the preferred trastuzumab products. Community will provide coverage for the preferred products for members meeting the Diagnosis-Specific Criteria in the policy.

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Herceptin, Ogivri, Ontruzant, Herzuma, Kanjinti and all other trastuzumab biosimilar products are non-preferred and subject to both Preferred Product Criteria and Diagnosis-Specific Criteria. Treatment with a non-preferred trastuzumab product is medically necessary for the indications specified in this policy when ALL of the following criteria are met:

1. Patient meets one of the following:
 - a) Both of the following:
 - History of a trial of preferred trastuzumab product resulting in minimal clinical response; AND
 - Physician attests that in his or her clinical opinion, the clinical response would be superior with a non-preferred trastuzumab product than the preferred product
 - b) Or, both of the following:
 - Patient has a history of intolerance, contraindication, or adverse event to preferred trastuzumab products; AND
 - Physician attests that in his or her clinical opinion the same intolerance, contraindication, or adverse event would not be expected to occur with non-preferred trastuzumab product; AND
2. Patient has not had a loss of a favorable response after established maintenance therapy with preferred trastuzumab product; AND
3. Patient meets the trastuzumab diagnosis-specific criteria for the requested indication.

Diagnosis-Specific Criteria

The term trastuzumab in the Diagnosis-Specific Criteria refers to Herceptin and all trastuzumab biosimilar products. Community utilizes InterQual clinical criteria to determine medical necessity of trastuzumab requests. Trastuzumab is medically necessary when the InterQual diagnosis-specific criteria for the below requested indications are met:

- Breast Cancer, Inflammatory
- Breast Cancer, Invasive
- Esophageal and Esophagogastric Junction Cancer
- Gastric Cancer
- Appendiceal Adenocarcinoma
- CNS – Brain Metastases, Limited
- CNS – Brain Metastases, Extensive
- CNS – Leptomeningeal Metastases
- Colon Cancer
- Endometrial Cancer
- Extrahepatic Cholangiocarcinoma
- Gallbladder Cancer
- Head and Neck Cancer, Salivary Gland
- Intrahepatic Cholangiocarcinoma
- Rectal Cancer

Applicable Codes

The following list(s) of procedure and/or diagnosis codes is provided for reference purposes only and may not be all inclusive.

HCPCS Code	Description
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg

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Q5117	Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg
Q5114	Injection, trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
Q5116	Injection, trastuzumab-qyyp, biosimilar, (Trazimera), 10 mg

Diagnosis Code	Description
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of lower third of esophagus
C15.8	Malignant neoplasm of overlapping sites of esophagus
C15.9	Malignant neoplasm of esophagus, unspecified
C16.0	Malignant neoplasm of cardia
C16.1	Malignant neoplasm of fundus of stomach
C16.2	Malignant neoplasm of body of stomach
C16.3	Malignant neoplasm of pyloric antrum
C16.4	Malignant neoplasm of pylorus
C16.5	Malignant neoplasm of lesser curvature of stomach, unspecified
C16.6	Malignant neoplasm of greater curvature of stomach, unspecified
C16.8	Malignant neoplasm of overlapping sites of stomach
C16.9	Malignant neoplasm of stomach, unspecified
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola, unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast

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C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C77.0	Secondary and unspecified malignant neoplasm of lymph nodes of head, face and neck
C77.1	Secondary and unspecified malignant neoplasm of intrathoracic lymph nodes

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C77.2	Secondary and unspecified malignant neoplasm of intra-abdominal lymph nodes
C77.3	Secondary and unspecified malignant neoplasm of axilla and upper limb lymph nodes
C77.4	Secondary and unspecified malignant neoplasm of inguinal and lower limb lymph nodes
C77.5	Secondary and unspecified malignant neoplasm of intrapelvic lymph nodes
C77.8	Secondary and unspecified malignant neoplasm of lymph nodes of multiple regions
C77.9	Secondary and unspecified malignant neoplasm of lymph node, unspecified
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.1	Secondary malignant neoplasm of mediastinum
C78.2	Secondary malignant neoplasm of pleura
C78.30	Secondary malignant neoplasm of unspecified respiratory organ
C78.39	Secondary malignant neoplasm of other respiratory organs
C78.4	Secondary malignant neoplasm of small intestine
C78.5	Secondary malignant neoplasm of large intestine and rectum
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C78.80	Secondary malignant neoplasm of unspecified digestive organ
C78.89	Secondary malignant neoplasm of other digestive organs
C79.00	Secondary malignant neoplasm of unspecified kidney and renal pelvis
C79.01	Secondary malignant neoplasm of right kidney and renal pelvis
C79.02	Secondary malignant neoplasm of left kidney and renal pelvis
C79.10	Secondary malignant neoplasm of unspecified urinary organs
C79.11	Secondary malignant neoplasm of bladder
C79.19	Secondary malignant neoplasm of other urinary organs
C79.2	Secondary malignant neoplasm of skin
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.40	Secondary malignant neoplasm of unspecified part of nervous system
C79.49	Secondary malignant neoplasm of other parts of nervous system
C79.51	Secondary malignant neoplasm of bone
C79.52	Secondary malignant neoplasm of bone marrow
C79.60	Secondary malignant neoplasm of unspecified ovary
C79.61	Secondary malignant neoplasm of right ovary
C79.62	Secondary malignant neoplasm of left ovary
C79.63	Secondary malignant neoplasm of bilateral ovaries
C79.70	Secondary malignant neoplasm of unspecified adrenal gland
C79.71	Secondary malignant neoplasm of right adrenal gland
C79.72	Secondary malignant neoplasm of left adrenal gland
C79.82	Secondary malignant neoplasm of genital organs

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C79.89	Secondary malignant neoplasm of other specified sites
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Policy Revision History

Status	Effective Date	Description
Baseline	4/01/2024	Initial version of Trastuzumab Preferred Product Policy
Revision 1	01/01/2025	Revised Preferred Product
Revision 2	02/13/2026	Revised Preferred Product