Trastuzumab Products

Policy # 00818
Original Effective Date: 12/12/2022
Current Effective Date: 07/01/2024

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc. (collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services Are Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider trastuzumab-dkst (Ogivri®)‡, and trastuzumab-qyyp (Trazimera™)‡, to be **eligible for coverage.****

When Services May Be Eligible for Coverage

Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider trastuzumab (Herceptin®)‡, trastuzumab-anns (Kanjinti™)‡, trastuzumab-pkrb (Herzuma®)‡, trastuzumab-dttb (Ontruzant®)‡, and trastuzumab and hyaluronidase-oysk (Herceptin Hylecta®) ‡ to be **eligible for coverage**** when the patient selection criterion is met.

Patient Selection Criteria

Coverage eligibility for the use of trastuzumab (Herceptin), trastuzumab-anns (Kanjinti), trastuzumab-pkrb (Herzuma), trastuzumab-dttb (Ontruzant), and trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) will be considered when the following criterion is met:

- Patient has tried and failed (e.g., intolerance or inadequate response) BOTH trastuzumab-dkst (Ogivri) AND trastuzumab-qyyp (Trazimera) unless there is clinical evidence or patient

history that suggests the use of these products will be ineffective or cause an adverse reaction to the patient.
*(Note: This specific patient selection criterion is an additional Company requirement for coverage eligibility and will be denied as not medically necessary** if not met).*

When Services Are Considered Not Medically Necessary

Based on review of available data, the Company considers the use of trastuzumab (Herceptin), trastuzumab-anns (Kanjinti), trastuzumab-pkrb (Herzuma), trastuzumab-dttb (Ontruzant), and trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) when the patient selection criterion is not met to be **not medically necessary.****

Background/Overview

The trastuzumab products (Herceptin, Ogivri, Kanjinti, Trazimera, Herzuma, Ontruzant, and Herceptin Hylecta) are approved by the Food and Drug Administration for a variety of oncolytic conditions. They also have off-label, yet acceptable, guideline driven uses.

Biosimilar products are biological products that are highly similar to and have no clinically meaningful differences from an existing FDA-approved reference product. In the case of the trastuzumab products, Herceptin is the FDA-approved reference product and Ogivri, Kanjinti, Trazimera, Herzuma, and Ontruzant are biosimilar products. As biosimilars, these products have been determined to have no clinically meaningful differences from Herceptin. Herceptin Hylecta is a formulation of Herceptin that has been developed to allow for subcutaneous administration of the product. It was determined in clinical trials to have similar efficacy and safety to intravenous Herceptin.

Rationale/Source

This medical policy was developed through consideration of peer-reviewed medical literature generally recognized by the relevant medical community, U.S. Food and Drug Administration approval status, nationally accepted standards of medical practice and accepted standards of medical practice in this community, technology evaluation centers, reference to federal regulations, other plan medical policies, and accredited national guidelines.

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The patient selection criterion in this policy takes into account clinical evidence or patient history that suggests the non-preferred trastuzumab products will be ineffective or cause an adverse reaction to the patient. Based on review of available data, in the absence of this caveat, there is no advantage of using the non-preferred trastuzumab products over the preferred products.

References

1. Herceptin [package insert]. Genentech, Inc. South San Francisco, California. Updated February 2021.
2. Ogivri [package insert]. Mylan Pharmaceuticals, Inc. Morgantown, West Virginia. Updated February 2021.
3. Kanjinti [package insert]. Amgen, Inc. Thousand Oaks, California. Updated October 2019.
4. Trazimera [package insert]. Pfizer. New York, New York. Updated November 2020.
5. Herzuma [package insert]. Celltrion, Inc. Republic of Korea. Updated May 2019.
6. Ontruzant [package insert]. Samsung Bioepis, Co. Republic of Korea. Updated March 2020.
7. Herceptin Hylecta [package insert]. Genentech, Inc. South San Francisco, California. Updated February 2019.
8. Primer on Biosimilars and Interchangeability. IPD Analytics. Updated Oct 2022.

Policy History

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11/03/2022	Medical Policy Committee review
11/09/2022	Medical Policy Implementation Committee approval. New policy.
11/02/2023	Medical Policy Committee review
11/08/2023	Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
04/04/2024	Medical Policy Committee review
04/10/2024	Medical Policy Implementation Committee approval. Updated policy to require trial of Ogivri and Trazimera prior to use of the other products.

Next Scheduled Review Date: 04/2025

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Coding

The five character codes included in the Blue Cross Blue Shield of Louisiana Medical Policy Coverage Guidelines are obtained from Current Procedural Terminology (CPT®)‡, copyright 2023 by the American Medical Association (AMA). CPT is developed by the AMA as a listing of descriptive terms and five character identifying codes and modifiers for reporting medical services and procedures performed by physician.

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CPT is a registered trademark of the American Medical Association.

Codes used to identify services associated with this policy may include (but may not be limited to) the following:

Code Type	Code
CPT	No Codes
HCPCS	J9355, J9356, Q5112, Q5113, Q5114, Q5116, Q5117
ICD-10 Diagnosis	All related Diagnoses

*Investigational – A medical treatment, procedure, drug, device, or biological product is Investigational if the effectiveness has not been clearly tested and it has not been incorporated into

standard medical practice. Any determination we make that a medical treatment, procedure, drug, device, or biological product is Investigational will be based on a consideration of the following:

A. Whether the medical treatment, procedure, drug, device, or biological product can be lawfully marketed without approval of the U.S. Food and Drug Administration (FDA) and whether such approval has been granted at the time the medical treatment, procedure, drug, device, or biological product is sought to be furnished; or
B. Whether the medical treatment, procedure, drug, device, or biological product requires further studies or clinical trials to determine its maximum tolerated dose, toxicity, safety, effectiveness, or effectiveness as compared with the standard means of treatment or diagnosis, must improve health outcomes, according to the consensus of opinion among experts as shown by reliable evidence, including:
    1. Consultation with technology evaluation center(s);
    2. Credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community; or
    3. Reference to federal regulations.

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. In accordance with nationally accepted standards of medical practice;
B. Clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. Not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

‡ Indicated trademarks are the registered trademarks of their respective owners.

NOTICE: If the Patient's health insurance contract contains language that differs from the BCBSLA Medical Policy definition noted above, the definition in the health insurance contract will be relied upon for specific coverage determinations.

NOTICE: Medical Policies are scientific based opinions, provided solely for coverage and informational purposes. Medical Policies should not be construed to suggest that the Company recommends, advocates, requires, encourages, or discourages any particular treatment, procedure, or service, or any particular course of treatment, procedure, or service.

NOTICE: Federal and State law, as well as contract language, including definitions and specific contract provisions/exclusions, take precedence over Medical Policy and must be considered first in determining eligibility for coverage.