OncoHealth

Trastuzumab: Herceptin, Herceptin Hylecta, Hercessi, Herzuma, Kanjinti, Ogivri, Ontruzant, Trazimera

Effective Date: 1/1/2024
Revision Date(s): 9/7/2023; 11/14/2023; 4/17/2024; 5/22/2024
Review Date: 5/22/2024
Policy type: Medical Necessity
Line of Business: Commercial

Authorizations are for 6 months, after which time they must be reviewed for efficacy, safety, and tolerability.

Preference	Requires Prior Auth	Drug Name	HCPCS Code	Description
Preferred	No	Trazimera	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg
Preferred	No	Kanjinti	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg
Non-Preferred	Yes	Herceptin	J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
Non-Preferred	Yes	Herceptin Hylecta	J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk
Non-Preferred	Yes	Hercessi	J9999	Not otherwise classified, antineoplastic drugs
Non-Preferred	Yes	Ontruzant	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
Non-Preferred	Yes	Herzuma	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
Non-Preferred	Yes	Ogivri	Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Members must have documentation of a contraindication, failure, or intolerance to any of the preferred agents prior to approval of a non-preferred product.				

Universal Criteria:

- Dose and frequency should be consistent with FDA labeling, NCCN, or indication specific peer-reviewed literature.; **AND**
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy or effectiveness, diminished effect, or an adverse event, the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Approval Criteria:

Unless otherwise noted above review criteria used by OncoHealth to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- New drugs or regimens (combinations of drugs) approved by the United States Food and Drug Administration (FDA).
- Drugs and biologics may be used off-label if they are considered medically accepted or necessary if supported by any of the following 5 compendia below.
    - NCCN Drugs & Biologics Compendium® (Category 1 and 2a)
    - Clinical Pharmacology (Strong For)
    - American Hospital Formulary Service Drug Information (AHFS DI) (Level 1)
    - Thompson Micromedex DrugDex® (Class I and IIa)
    - Wolters Kluwer Lexi-Drugs® (Level A)
- Other uses of drugs and biologics may be considered medically accepted if supported as safe and effective according to peer-reviewed articles from one of the following journals
    - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology
    - **Meeting abstracts and case reports are excluded from consideration.**
- Non-standard protocols may be approved based on unique clinical circumstances.

Billing

Drug Name	HCPCS Code	Description
Herceptin	J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
Herceptin Hylecta	J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk
Hercessi	J9999	Noth otherwise classified, antineoplatic drugs
Ontruzant	Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
Herzuma	Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
Ogivri	Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Trazimera	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg
Kanjinti	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg

References

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2. Herceptin Hylecta [package insert]. Genentech, Inc., South San Francisco, CA. Available at: https://www.gene.com/download/pdf/herceptin_hylecta_prescribing.pdf

3. Herzuma® [package insert]. Teva Pharmaceuticals USA, Inc., North Wales, PA. Available at: https://www.herzumahcp.com/globalassets/herzuma-consumer/pdfs/herzuma-prescribing-information.pdf
4. Hercessi™ [package insert]. Accord BioPharmac Inc., Raleigh, NC. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761346Orig1s000lbl.pdf
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9. Trastuzumab. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
10. Trastuzumab and hyaluronidase-oysk. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/
11. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®). National Comprehensive Cancer Network, Inc. 2024. All rights reserved. Accessed May 22nd, 2024. To view the most recent and complete version of the guideline, go online to NCCN.org.

Disclaimer

Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Category 1 or 2A recommendations), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine. OncoHealth reserves the right to request medical documentation as needed to validate medical necessity determinations.

Drug Coverage Policies are developed as needed, regularly reviewed, updated at least annually, and are subject to change. Other policies and coverage determination guidelines may apply. Federal and state regulatory requirements and member specific benefit plan documents, if applicable, must be reviewed prior to this Drug Coverage Policy. This Drug Coverage Policy is for informational purposes only and does not constitute medical advice or dictate how providers should practice medicine. This policy should not be reproduced, stored in a retrieval system, or altered from its original form without written permission from OncoHealth, Inc.

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Date	Updates
11/14/2023	Updated Step Therapy to Table, Added Universal Criteria, Updated References, Updated footer
4/17/2024	Updated Universal Criteria
5/22/2024	Addition of Hercessi