brand new day
HEALTHCARE YOU CAN FEEL GOOD ABOUT

CENTRAL HEALTH MEDICARE PLAN

Medical Policy

Antineoplastic – trastuzumab [Herceptin® (trastuzumab), Herceptin Hylecta® (trastuzumab and hyaluronidase-oysk), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ontruzant®(trastuzumab-dttb), Ogivri® (trastuzumab-dkst), Trazimera® (trastuzumab-q)]	
MEDICAL POLICY NUMBER	MED_Clin_Ops_044b
POLICY OWNER	Policy Owner Name First Last
ORIGINAL EFFECTIVE DATE	7/1/2021
CURRENT VERSION NUMBER	3
CURRENT VERSION EFFECTIVE DATE	1/1/2024
APPLICABLE PRODUCT AND MARKET	Medicare Advantage: ALL

***IMPORTANT INFORMATION – PLEASE READ BEFORE USING THIS POLICY**: These services may or may not be covered by all Brand New Day/Central Health Medicare Plan. Please refer to the member's plan document for specific coverage information.*

Brand New Day/Central Health Medicare Plan may use tools developed by third parties, such as MCG™ Care Guidelines and the ASAM Criteria™ to assist in administering health benefits. Brand New Day/Central Health Medicare Plan Medical Policies, MCG™ Care Guidelines, and the ASAM Criteria™ are not intended to be used without the independent clinical judgment of a qualified health care provider considering the individual circumstances of each member's case. The treating health care providers are solely responsible for diagnosis, treatment, and medical advice.
Members may contact Brand New Day/Central Health Medicare Plan Customer Service at the phone number listed on their member identification card to discuss their benefits more specifically. Providers with questions about this Brand New Day/ Central Health Medicare Plan policy may contact the Health Plan.

Before using this policy, please check the member benefit plan document and any federal or state mandates, if applicable. Brand New Day/Central Health Medicare Plan policies and practices are compliant with all federal and state requirements, including mental health parity laws.

PURPOSE

To promote consistency between reviewers in clinical coverage decision-making by providing the criteria that generally determine the medical necessity of trastuzumab therapy.

POLICY/CRITERA

Prior Authorization and Medical Review is required.

Coverage will be provided for six months and may be renewed. Use in the adjuvant setting is limited to a total of 52 weeks of treatment.

Medical Policy

Herceptin, Herceptin Hylecta, Ogivri ,Herzuma, Ontruzant are Non-Preferred products.
The Preferred products are Kanjinti and Trazimera.

Herceptin, Herceptin Hylecta, Ogivri ,Herzuma, Ontruzant may be considered medically necessary if:

- Patient has experienced a therapeutic failure or intolerance with Kanjinti **AND** Trazimera; **OR**
- Herceptin, Herceptin Hylecta, Ogivri ,Herzuma, Ontruzant is requested for an indication for which Kanjinti **AND** Trazimera have not been FDA-approved

Coverage for Herceptin® (trastuzumab), Herceptin Hylecta® (trastuzumab and hyaluronidase-oysk), Herzuma® (trastuzumab-pkrb), Kanjinti® (trastuzumab-anns), Ontruzant®(trastuzumab-dttb), Ogivri® (trastuzumab-dkst), Trazimera® (trastuzumab-qyyp) is provided in the following conditions:

1. Patient is 18 years of age or older; **AND**
2. Baseline left ventricular ejection fraction (LVEF) within normal limits; **AND**
3. Patient's cancer is human epidermal growth factor receptor 2 (HER2)-positive; **AND**

Breast Cancer

1. Requested drug is being used as adjuvant therapy for HER2 overexpressing* breast cancer:
    a. as part of a treatment regimen consisting of doxorubicin, cyclophosphamide, and either paclitaxel or docetaxel; **OR**
    b. as part of a treatment regimen with docetaxel and carboplatin; **OR**
    c. as a single agent following multi-modality anthracycline based therapy; **OR**
2. Requested drug is being used for metastatic HER2-overexpressing* breast cancer; **AND**
    a. Requested drug is being used as a single agent in patients who have received one or more chemotherapy regimens for metastatic disease; **OR**
    b. Requested drug is being used as first-line therapy in combination with paclitaxel.

Gastric, Esophageal and Esophagogastric Junction Cancers (EXCLUDING Herceptin Hylecta)

1. Patient has a diagnosis of HER2-overexpressing* metastatic gastric or gastroesophageal junction adenocarcinoma; **AND**
2. Requested drug is being used in combination with cisplatin and capecitabine or 5-fluorouracil; **AND**
3. Patient has not received prior treatment for metastatic disease.

*HER2-positive overexpression criteria:

- Immunohistochemistry (IHC) assay 3+; **OR**
- Fluorescence in situ hybridization (FISH) assay ≥2.0 (HER2/CEP17 ratio); **OR**
- Average HER2 copy number ≥ 6 signals/cell

DOSING LIMITS

Max Units (per dose and over time) [Medical Benefit]:

Breast Cancer and Gastric/Esophageal/Gastro-esophageal junction Cancers

	150 mg SDV Load MU	150 mg SDV Maintenance MU
7-day dosing schedule	45	30
21-day dosing schedule	90	75

LIMITATIONS/EXCLUSIONS

1. Any indication other than those listed above due to insufficient evidence of therapeutic value.

DEFINITIONS

1. HERCEPTIN (trastuzumab) for injection, for intravenous use. Initial U.S. Approval: 1998
    a. Herceptin (trastuzumab) for injection 150 mg/vial is supplied in a single-dose vial as a lyophilized sterile powder, under vacuum. Available in a carton containing one single-dose vial
2. OGIVRI (trastuzumab-dkst) for injection, for intravenous use. Initial U.S. Approval: 2017
    a. OGIVRI (trastuzumab-dkst) is biosimilar* to HERCEPTIN (trastuzumab).
    b. Ogivri (trastuzumab-dkst) for injection 420 mg/vial is supplied in a multiple-dose vial as an off-white to pale yellow lyophilized sterile powder, under vacuum. Each carton contains one multiple-dose vial of Ogivri and one vial (20 mL) of Bacteriostatic Water for Injection (BWFI), USP, containing 1.1% benzyl alcohol as a preservative.
    c. Ogivri (trastuzumab-dkst) for injection 420 mg/vial is supplied in a multiple-dose vial as an off-white to pale yellow lyophilized sterile powder, under vacuum. Each carton contains one multiple-dose vial of Ogivri. No diluent is provided.
    d. Ogivri (trastuzumab-dkst) for injection 150 mg/vial is supplied in a single-dose vial as an off-white to pale yellow lyophilized sterile powder, under vacuum. Each carton contains one single-dose vial of Ogivri.
3. HERZUMA (trastuzumab-pkrb) for injection, for intravenous use. Initial U.S. Approval: 2018
    a. HERZUMA (trastuzumab-pkrb) is biosimilar to HERCEPTIN (trastuzumab).
    b. HERZUMA (trastuzumab-pkrb) for injection 420 mg/vial is supplied in a multiple-dose vial
    c. HERZUMA (trastuzumab-pkrb) for Injection 150 mg/vial is supplied in a single-dose vial
4. TRAZIMERA™ (trastuzumab-qyyp) for injection, for intravenous use. Initial U.S. Approval: 2019
    a. TRAZIMERA (trastuzumab-qyyp) is biosimilar to HERCEPTIN (trastuzumab).
    b. TRAZIMERA (trastuzumab-qyyp) for injection 420 mg/vial is supplied in a multiple-dose vial as a sterile, white lyophilized powder. Each carton contains one multiple-dose vial of TRAZIMERA and one vial (20 mL) of Bacteriostatic Water for Injection (BWFI) containing 1.1% benzyl alcohol as a preservative.

   c. TRAZIMERA (trastuzumab-qyyp) for injection 150 mg/vial is supplied in a single-dose vial as a sterile, white lyophilized powder. Each carton contains one single-dose vial of TRAZIMERA.
5. ONTRUZANT (trastuzumab-dttb) for injection, for intravenous use. Initial U.S. Approval: 2019
   a. ONTRUZANT (trastuzumab-dttb) is biosimilar to HERCEPTIN (trastuzumab)
   b. Ontruzant (trastuzumab-dttb) for injection 420 mg/vial is supplied in a multiple-dose vial as a white to pale yellow lyophilized sterile powder, under vacuum. Each carton contains one multiple-dose vial of Ontruzant and one vial (20 mL) of Bacteriostatic Water for Injection (BWFI), USP, containing 1.1% benzyl alcohol as a preservative.
   c. Ontruzant (trastuzumab-dttb) for injection 150 mg/vial is supplied in a single-dose vial as a white to pale yellow lyophilized sterile powder, under vacuum. Each carton contains one single-dose vial of Ontruzant.
6. KANJINTI™ (trastuzumab-anns) for injection, for intravenous use. Initial U.S. Approval: 2019
   a. KANJINTI (trastuzumab-anns) is biosimilar* to HERCEPTIN (trastuzumab)
   b. KANJINTI (trastuzumab-anns) for injection 420 mg/vial is supplied in a multiple-dose vial as a white to pale yellow lyophilized sterile powder, under vacuum. Each carton contains one multiple-dose vial of KANJINTI.
   c. KANJINTI (trastuzumab-anns) for injection 150 mg/vial is supplied in a single-dose vial as a white to pale yellow lyophilized sterile powder, under vacuum. Each carton contains one single-dose vial of KANJINTI
7. HERCEPTIN HYLECTA™ (trastuzumab and hyaluronidase-oysk) injection, for subcutaneous use. Initial U.S. Approval: 2019
   a. HERCEPTIN HYLECTA (trastuzumab and hyaluronidase-oysk) injection for subcutaneous use supplied as a sterile, preservative-free, colorless to yellowish, clear to opalescent solution in a single-dose vial.
   b. Individually packaged single-dose vials: HERCEPTIN HYLECTA 600 mg/10,000 units (NDC: 50242-077-01) providing 600 mg trastuzumab and 10,000 units hyaluronidase per 5 mL.

CODING

Applicable NDC Codes	
50242-0132-xx	Herceptin 150 mg SDV; powder for injection
50242-0077-01	Herceptin Hylecta 600 mg/10,000 units providing 600 mg trastuzumab and 10,000 units hyaluronidase per 5 mL.
63459-0303-xx	Herzuma 150 mg single-dose vial; powder for injection
63459-0305-47	Herzuma (trastuzumab-pkrb) for Injection 420 mg/vial, multi-dose vial
67457-0847-44	Ogivri (trastuzumab-dkst) for injection 420 mg/vial, multi-dose vial
67457-0991-xx	Ogivri 150 mg single-dose vial; powder for injection
00006-5033-02	Ontruzant (trastuzumab-dttb) for injection 150 mg/vial, single-dose vial
00006-5034-xx	Ontruzant 420 mg multiple-dose vial; powder for injection
55513-0132-01	vial, 1 each Trastuzumab (Kanjinti) 420mg, Lyophilisate for solution for injection

55513-0141-xx	Kanjinti 150 mg single-dose vial powder for injection
00069-0305-01	Trazimera (trastuzumab-qyyp) injection 420 mg/vial, multiple-dose vial
00069-0308-xx	Trazimera 150 mg single-dose vial; lyophilized powder for injection

Applicable Procedure Code	
J9355	Injection, trastuzumab, 10 mg; 1 billable unit = 10mg
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk: 1 billable unit = 10 mg
Q5113	Injection, trastuzumab-pkrb, biosimilar, (Herzuma), 10 mg
Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5112	Injection, trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg
Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg, effective 10/01/2019
Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg, effective 10/01/2019

Applicable ICD-10 Codes	
C15.3	Malignant neoplasm of upper third of esophagus
C15.4	Malignant neoplasm of middle third of esophagus
C15.5	Malignant neoplasm of the 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 female breast
C50.022	Malignant neoplasm of nipple and areola, left female breast
C50.029	Malignant neoplasm of nipple and areola, unspecified female 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

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
D37.1	Neoplasm of uncertain behavior of stomach
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.3	Personal history of malignant neoplasm of breast

EVIDENCE BASED REFERENCES

1. Herceptin [package insert]. South San Francisco, CA; Genentech, Inc; April 2017. Accessed May 2021.
2. Product Information: HERCEPTIN HYLECTA(TM) subcutaneous injection, trastuzumab hyaluronidase-oysk subcutaneous injection. Genentech Inc (per FDA), South San Francisco, CA, 2019.
3. Product Information: OGIVRI intravenous injection, trastuzumab-dkst intravenous injection. Mylan Pharmaceuticals, Inc (per FDA), Morgantown, WV, 2017.
4. Product Information: ONTRUZANT intravenous injection, trastuzumab-dttb intravenous injection. Merck Sharp & Dohme Corp (per FDA), Whitehouse Station, NJ, 2019.
5. Product Information: HERZUMA(R) intravenous injection, trastuzumab-pkrb intravenous injection. Teva Pharmaceuticals, Inc (per FDA), North Wales, PA, 2018.
6. Product Information: KANJINTI(TM) intravenous injection, trastuzumab-anns intravenous injection. Amgen Inc (per FDA), Thousand Oaks, CA, 2019.
7. Product Information: TRAZIMERA(TM) intravenous injection, trastuzumab-qyyp intravenous injection. Pfizer Labs (per FDA), New York, NY, 2019

POLICY HISTORY

Revision History	Month Day, Year	Updates
Original Effective Date	JULY 1, 2021	
Revision	JANUARY 1, 2022	Mandatory Step Therapy effective starting January 1, 2022 (grandfathering in place for members on therapy)
	January 1, 2024	Updated to Brand New Day/Central Health Medicare Plan
P&T Committee Endorsement	MAY 24, 2021	

DISCLAIMER

Brand New Day/Central Health Medicare Plan medical policies address technology assessment of new and emerging treatments, devices, drugs, etc. They are developed to assist in administering plan benefits and do not constitute an offer of coverage nor medical advice. Brand New Day/Central Health Medicare Plan medical policies contain only a partial, general description of plan or program benefits and do not constitute a contract. Brand New Day/Central Health Medicare Plan does not provide health care services and, therefore, cannot guarantee any results or outcomes. Treating providers are solely responsible for medical advice and treatment of members. Our medical policies may be updated and therefore are subject to change without notice. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). MCG™ and Care Guidelines® are trademarks of MCG Health, LLC (MCG). The ASAM Criteria™ is copyrighted by The American Society of Addiction Medicine.