Trastuzumab:

Herceptin®; Ogivri®; Kanjinti®; Trazimera™; Herzuma®; Ontruzant®; Hercessi™; Trastuzumab-pkrb§(Intravenous)

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I. Length of Authorization [1-6,8]

- Initial: Prior authorization validity will be provided initially for 6 months.
- Renewal: Prior authorization validity may be renewed every 6 months thereafter, unless otherwise specified.
  - Neoadjuvant/preoperative and adjuvant treatment in Breast Cancer: Prior authorization validity may be renewed up to a maximum of fifty-two (52) weeks of treatment.

II. Dosing Limits

1. Max Units (per dose and over time) [HCPCS Unit]:

- Ogivri, Kanjinti, Trazimera, Herzuma/Trastuzumab-pkrb, Ontruzant, Hercessi (420 mg MDV):
  - Gastric, Esophageal, and Esophagogastric Junction Cancer:
    - Load: 92 billable units x 1 dose
    - Maintenance: 138 billable units every 42 days
  - CNS Cancer:
    - Load: 92 billable units x 1 dose
    - Maintenance: 207 billable units every 21 days
  - Breast Cancer, Colorectal Cancer, Appendiceal Adenocarcinoma, Head and Neck Cancers, & All other indications:
    - Load: 92 billable units x 1 dose
    - Maintenance: 69 billable units every 21 days
- Herceptin (150 mg SDV):

- Gastric, Esophageal, and Esophagogastric Junction Cancer:
  - Load: 90 billable units x 1 dose
  - Maintenance: 150 billable units every 42 days
- CNS Cancer:
  - Load: 90 billable units x 1 dose
  - Maintenance: 225 billable units every 21 days
- Breast Cancer, Colorectal Cancer, Appendiceal Adenocarcinoma, & Head and Neck Cancers: 90 billable units every 21 days
- All other indications:
  - Load: 90 billable units x 1 dose
  - Maintenance: 75 billable units every 21 days

III. Initial Approval Criteria [1-7]

Coverage is provided in the following conditions:

Requests for Herceptin, Herzuma, Kanjinti, or Ontruzant:

- Patients must have failed, or have a contraindication or intolerance to Ogivri (trastuzumab-dkst) AND Trazimera (trastuzumab-qyyp); **AND**

- Patient is at least 18 years of age; **AND**

Universal Criteria [1-7]

- Left ventricular ejection fraction (LVEF) is within normal limits prior to initiating therapy and will be assessed at regular intervals (e.g., every 3 months) during treatment; **AND**
- Patient has human epidermal growth factor receptor 2 (HER2)-positive* disease as determined by an FDA-approved or CLIA-compliant test, unless otherwise specified❖; **AND**
- Females of reproductive potential have a negative pregnancy test prior to initiating treatment and will use effective contraception during treatment and for 7 months after the last dose; **AND**
- Therapy will not be substituted with or for ado-trastuzumab emtansine (Kadcyla) or fam-trastuzumab deruxtecan-nxki (Enhertu); **AND**
- Therapy will not be used in combination with trastuzumab and hyaluronidase-oysk (Herceptin Hylecta) or pertuzumab/trastuzumab and hyaluronidase-zzxf (Phesgo); **AND**

Breast Cancer † ‡ [1-9,11-17,36-39,44,45,54,10e,11e,13e,14e,16e,17e,19e,20e]

- Used as adjuvant therapy; **AND**
  - Patient has ≥ T1 disease, node positive disease, or inflammatory disease (unless otherwise specified); **AND**

        - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) WITH pertuzumab (pN+ ONLY); **OR**
        - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) WITHOUT pertuzumab; **OR**
        - Used in combination with pertuzumab (pN+ ONLY); **OR**
        - Used as a single agent; **OR**
    - Used after completion of planned chemotherapy and following mastectomy or breast-conserving surgery; **AND**
        - Patient has ≥ ypT0N0 or pCR disease by axillary staging; **AND**
            - Used as a single agent; **OR**
            - Used in combination with pertuzumab (cN+ ONLY); **OR**
- Used as neoadjuvant or preoperative therapy; **AND**
    - Patient has ≥ T1c disease, node positive disease, or inflammatory disease; **AND**
    - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) with or without pertuzumab; **OR**
- Used for recurrent unresectable (local or regional) or metastatic disease OR inflammatory breast cancer, unless otherwise specified; **AND**
    - Used as a single agent in patients who have received one or more prior chemotherapy regimens for metastatic disease **†**; **OR**
    - Used in combination with one of the following:
        - Paclitaxel as first-line therapy for metastatic disease **†**
        - Tamoxifen, fulvestrant, or aromatase inhibition with or without lapatinib in patients with hormone receptor-positive disease; **AND**
            - Patient is postmenopausal; **OR**
            - Patient is premenopausal and is treated with ovarian ablation/suppression; **OR**
            - Patient is premenopausal and will not receive ovarian ablation/suppression *(with tamoxifen ONLY)*; **OR**
            - Patient is a male (sex assigned at birth) **¥**
        - Neratinib and fulvestrant as third-line therapy and beyond in patients with HER2 activating mutations (for use in metastatic disease only); **AND**
            - Patient has hormone receptor-positive, HER2 negative disease; **AND**
                - Patient has already received CDK4/6 inhibitor therapy
        - Pertuzumab and a taxane (e.g., docetaxel, paclitaxel) as first-line therapy
        - Capecitabine and tucatinib as second-line therapy and beyond after prior HER2-directed therapy with trastuzumab, pertuzumab, AND ado-trastuzumab emtansine, unless contraindicated

- Cytotoxic chemotherapy as fourth-line therapy and beyond
- Lapatinib (without cytotoxic therapy) as fourth-line therapy and beyond after prior anti-HER2 directed therapy for metastatic disease, unless contraindicated
- Pertuzumab with or without cytotoxic therapy as subsequent therapy in patients previously treated with chemotherapy and trastuzumab (without pertuzumab); **AND**

Fourth-line therapy and beyond in combination with pertuzumab with or without cytotoxic therapy:

- Patient must demonstrate an inadequate response to one of the following regimens, unless there is a contraindication or intolerance, prior to approval of trastuzumab:
  - Lapatinib/capecitabine
  - Trastuzumab/lapatinib
  - Trastuzumab/generically available agent(s) (e.g., trastuzumab/capecitabine, etc. [*see NCCN Breast Cancer guidelines for complete list of alternative regimens*]

¥ *When an aromatase inhibitor is used in males, suppression of testicular steroidogenesis with a GnRH analog is required.*

Central Nervous System (CNS) Cancer ‡ [8,19,30-31]

- Patient has leptomeningeal metastases from breast cancer; **AND**
  - Trastuzumab will be administered intrathecally or intraventricularly; **AND**
    - Used as primary treatment in patients with good risk status (i.e., KPS ≥60, no major neurologic deficits, minimal systemic disease, and reasonable systemic treatment options if needed); **OR**
    - Used as maintenance therapy in patients with negative CSF cytology or in clinically stable patients with persistently positive CSF cytology; **OR**
- Patient has brain metastases from breast cancer; **AND**
  - Used in combination with capecitabine and tucatinib in patients previously treated with trastuzumab, pertuzumab, AND ado-trastuzumab, unless contraindicated; **AND**
  - Used in one of the following treatment settings:
    - Used as initial treatment in patients with small asymptomatic brain metastases
    - Patient has recurrent limited brain metastases
    - Patient has recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options
    - Patient has relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options

Gastric, Esophageal, and Esophagogastric Junction Cancers † ‡ Φ [1-8,18,33,34,51,34e,35e]

- Patient has adenocarcinoma; **AND**

- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease; **AND**
- Used as first-line therapy; **AND**
  - Used in combination with chemotherapy; **OR**
  - Used in combination with pembrolizumab AND fluorouracil or capecitabine AND oxaliplatin or cisplatin; **AND**
    - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖

Endometrial Carcinoma – Uterine Neoplasms ‡ [8,20,35]

- Used in combination with carboplatin and paclitaxel, followed by single agent maintenance therapy; **AND**
- Patient has uterine serous carcinoma; **AND**
  - Patient has stage III/IV disease; **OR**
  - Patient has recurrent disease and has not received prior trastuzumab therapy; **AND**
    - Used as first-line therapy; **AND**
      - Patient does not have isolated metastases; **OR**
    - Used as subsequent therapy

Colorectal Cancer (CRC) λ ‡ [8,10,32,21e,22e]

- Patient has RAS and BRAF wild-type (WT) disease; **AND**
- Used in one of the following:
  - Used as initial treatment for unresectable metastatic disease and previous FOLFOX or CapeOX within the past 12 months; **AND**
    - Used in combination with lapatinib; **OR**
    - Used in combination with pertuzumab; **AND**
      - Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with pertuzumab; **OR**
    - Used in combination with tucatinib; **AND**
      - Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with tucatinib; **OR**
  - Used as primary treatment for unresectable (or medically inoperable) or metastatic disease if intensive therapy is not recommended; **AND**
    - Patient has not previously received HER2-directed therapy; **AND**

- Used in combination with lapatinib; **OR**
- Used in combination with pertuzumab; **AND**

> ➢ Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with pertuzumab; **OR**

- Used in combination with tucatinib; **AND**

> ➢ Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with tucatinib; **OR**

- Used as primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or locally unresectable (or medically inoperable) rectal cancer if intensive therapy is not recommended; **AND**
  - Used in combination with lapatinib; **AND**
    - Used if resection is contraindicated following total neoadjuvant therapy; **OR**
    - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **OR**
  - Used in combination with pertuzumab; **AND**

> – Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with pertuzumab; **AND**

    - ➢ Used if resection is contraindicated following total neoadjuvant therapy; **OR**
    - ➢ Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **OR**
  - Used in combination with tucatinib; **AND**

> – Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with tucatinib; **AND**

    - ➢ Used if resection is contraindicated following total neoadjuvant therapy; **OR**
    - ➢ Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **OR**
- Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
  - Used in combination with pertuzumab, lapatinib, or tucatinib; **AND**
  - Patient has not previously received HER2-directed therapy; **AND**

- In combination with pertuzumab ONLY:

➢ Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with pertuzumab

λ Note: NCCN recommends universal MMR or MSI testing in all newly diagnosed patients. If deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) or polymerase epsilon/delta (POLE/POLD1) mutation with ultra-hypermutated phenotype (e.g., TMB>50 mut/Mb), treatment should include checkpoint inhibitor immunotherapy if the patient is a candidate.

Appendiceal Adenocarcinoma – Colon Cancer λ ‡ [8,10]

- Patient has RAS and BRAF wild-type (WT) disease; **AND**
- Patient has not previously received HER2-targeted therapy; **AND**
- Used for one of the following:
  - Used as initial therapy for advanced or metastatic disease if intensive therapy is not recommended; **OR**
  - Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
- Used for one of the following:
  - Used in combination with lapatinib; **OR**
  - Used in combination with pertuzumab; **AND**
    - Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with pertuzumab; **OR**
  - Used in combination with tucatinib; **AND**
    - Patient must demonstrate an inadequate response to trastuzumab/lapatinib, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with tucatinib

Head and Neck Cancers ‡ [8,40-43]

- Patient has salivary gland tumors; **AND**
- Used in combination with either docetaxel or pertuzumab; **AND**
- Patient has recurrent disease with one of the following:
  - Distant metastases
  - Unresectable locoregional recurrence with prior radiation therapy (RT)
  - Unresectable second primary with prior RT; **AND**

- In combination with pertuzumab ONLY:

- Patient must demonstrate an inadequate response to trastuzumab/docetaxel, unless there is a contraindication or intolerance, prior to approval of trastuzumab in combination with pertuzumab

Biliary Tract Cancers (Gallbladder Cancer or Intra-/Extra-Hepatic Cholangiocarcinoma) ‡ [8,46,47,52,44e]

- Used as subsequent treatment for progression on or after systemic treatment for unresectable, gross residual (R2), or metastatic disease; **AND**
- Used in combination with pertuzumab or tucatinib
-

*HER2-positive overexpression criteria
Breast, CNS, Uterine, and Head and Neck Cancer: [9,11]

• Immunohistochemistry (IHC) assay 3+; **OR**
• Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number ≥ 4.0 signals/cell; **OR**
• Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:
  ○ HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR**
  ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR**
  ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+

Biliary Tract Cancer [9,11,47]

• Immunohistochemistry (IHC) assay 3+; **OR**
• Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number ≥ 4.0 signals/cell; **OR**
• Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:
  ○ HER2/CEP17 ratio ≥ 2.0 AND average HER2 copy number < 4.0 signals/cell AND concurrent IHC 3+; **OR**
  ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+ or 3+; **OR**
  ○ HER2/CEP17 ratio < 2.0 AND average HER2 copy number ≥ 4.0 and < 6.0 signals/cell AND concurrent IHC 3+; **OR**
• Next-generation sequencing (NGS) panel HER2 amplification

Gastric, Esophageal, and Esophagogastric Junction Cancer: [33,34]

• Immunohistochemistry (IHC) assay 3+; **OR**
• Fluorescence in situ hybridization (FISH) or in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:
  ○ HER2/CEP17 ratio ≥ 2.0 AND concurrent IHC 2+; **OR**
  ○ Average HER2 copy number ≥ 6.0 signals/cell AND concurrent IHC 2+; **OR**

• Next-generation sequencing (NGS) panel HER2 amplification
Colorectal Cancer and Appendiceal Adenocarcinoma: [10,32]
• Immunohistochemistry (IHC) assay 3+; **OR** • Fluorescence in situ hybridization (FISH) HER2/CEP17 ratio ≥ 2 AND concurrent IHC 2+; **OR** • Next-generation sequencing (NGS) panel HER2 amplification

•

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

Enhanced Oncology Value (EOV) Program – Redacted indications
Uses not listed above have inadequate data to support efficacy and are excluded from coverage. Other treatment options including, but are not limited to, the following may be appropriate: radiation therapy, surgery, traditional chemotherapy (e.g., platinum, taxane), compassionate use/expanded access programs, clinical trials, supportive care, integrative and complementary therapies.

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/companiondiagnostics*

† FDA Approved Indication(s); ‡ Compendia Recommended Indication(s); Φ Orphan Drug

IV. Renewal Criteria [1-7]

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Duration of authorization has not been exceeded *(refer to Section I)*; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: cardiomyopathy (e.g., left ventricular cardiac dysfunction, arrhythmias, cardiac failure, etc.), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis, pulmonary infiltrates, pleural effusions, etc.), severe or febrile neutropenia, severe infusion-related reactions, etc.; **AND**
- Left ventricular ejection fraction (LVEF) obtained within the previous 3 months as follows:
    - LVEF is within the institutional normal limits, and has not had an absolute decrease of ≥ 16% from pre-treatment baseline; **OR**

- LVEF is below the institutional lower limits of normal, and has not had an absolute decrease of ≥ 10% from pre-treatment baseline

V. Dosage/Administration [1-9,19,20,30,32-34,41-43,46,50,52-56]

Indication	Dose
Breast Cancer	**Neoadjuvant/Preoperative or Adjuvant Therapy** Loading dose: 4 mg/kg intravenously x 1 for every 7-day dosing schedule Maintenance dose: 2 mg/kg intravenously every 7 days **OR** Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule Maintenance dose: 6 mg/kg intravenously every 21 days *Note: Use for neoadjuvant/preoperative and adjuvant treatment is limited to a total of 52 weeks of treatment.* **Recurrent, Unresectable, Metastatic Disease OR Inflammatory breast cancer** Loading dose: 4 mg/kg intravenously x 1 for every 7-day dosing schedule Maintenance dose: 2 mg/kg intravenously every 7 days **OR** Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule Maintenance dose: 6 mg/kg intravenously every 21 days *Note: Treat until disease progression or intolerable toxicity.*
Gastric, Esophageal, and Esophagogastric Junction Cancers	Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule Maintenance dose: 6 mg/kg intravenously every 21 days **OR** Loading dose: 6 mg/kg intravenously x 1 for every 14-day dosing schedule Maintenance dose: 4 mg/kg intravenously every 14 days *Note: Treat until disease progression or intolerable toxicity.*
Colorectal Cancer, Appendiceal Adenocarcinoma, Head and Neck Cancers	Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule Maintenance dose: 6 mg/kg intravenously every 21 days **OR** Loading dose: 4 mg/kg intravenously x 1 for every 7-day dosing schedule Maintenance dose: 2 mg/kg intravenously every 7 days *Note: Treat until disease progression or intolerable toxicity.*
CNS Cancer	**Leptomeningeal Metastases from Breast Cancer** Escalating doses up to 150 mg intrathecally or intraventricularly weekly* **Dosing is highly variable and should be individualized*. **Limited or Extensive Brain Metastases from Breast Cancer** Combination Therapy with capecitabine and tucatinib

	–Administer an initial dose at 8 mg/kg intravenously followed by 6 mg/kg intravenously every 21 days *Note: Treat until disease progression or intolerable toxicity.*
All other indications	Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule Maintenance dose: 6 mg/kg intravenously every 21 days *Note: Treat until disease progression or intolerable toxicity.*

VI. Billing Code/Availability Information

Brand Name	HCPCS	HCPCS Description	1 BU	Vial Size & Type	NDCs
Herceptin	J9355	Injection, trastuzumab, excludes biosimilar, 10 mg	10 mg	150 mg SDV	50242-0132-xx
				420 mg MDV (*discontinued*)	50242-0333-xx (*discontinued*)
Ogivri	Q5114	Injection, trastuzumab-dkst, biosimilar, (ogivri), 10 mg	10 mg	150 mg SDV	83257-0001-xx
				420 mg MDV (with diluent)	83257-0004-xx
				420 mg MDV (no diluent)	83257-0003-xx
Kanjinti	Q5117	Injection, trastuzumab-anns, biosimilar, (kanjinti), 10 mg	10 mg	150 mg SDV	55513-0141-xx
				420 mg MDV (with diluent)	55513-0164-xx
				420 mg MDV (no diluent)	55513-0132-xx
Trazimera	Q5116	Injection, trastuzumab-qyyp, biosimilar, (trazimera), 10 mg	10 mg	150 mg SDV	00069-0308-xx
				420 mg MDV	00069-0305-xx
Herzuma	Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg	10 mg	150 mg SDV	63459-0303-xx
				420 mg MDV	63459-0305-xx
Trastuzumab-pkrb§ *(unbranded biologic of Herzuma)*	Q5113	Injection, trastuzumab-pkrb, biosimilar, (herzuma), 10 mg	10 mg	150 mg SDV	51759-0225-xx
				420 mg MDV	51759-0226-xx
Ontruzant	Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg	10 mg	150 mg SDV	78206-0147-xx
				420 mg MDV	78206-0148-xx
Hercessi	Q5146	Injection, trastuzumab-strf (hercessi), biosimilar, 10 mg	10 mg	150 mg SDV	69448-0015-xx
				420 mg MDV	69448-0016-xx

Notes:

- Herceptin is only available as a single-dose vial; therefore, the JW modifier is allowed
- Ogivri, Kanjinti, Trazimera, Herzuma, Hercessi & Ontruzant are available as both single-dose and multi-dose vials. Approvals are based upon use of the MDV; therefore, the JW modifier is not allowed
- §An unbranded biologic is the same as the brand biologic and uses the same cell-line as the brand-name reference biologic

VII. References (STANDARD)

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8. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) trastuzumab. National Comprehensive Cancer Network, 2025. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN GUIDELINES® are trademarks owned by the National Comprehensive Cancer Network, Inc. To view the most recent and complete version of the Compendium, go online to NCCN.org. Accessed July 2025.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
C06.9	Malignant neoplasm of mouth, unspecified
C07	Malignant neoplasm of parotid gland
C08.0	Malignant neoplasm of submandibular gland
C08.1	Malignant neoplasm of sublingual gland
C08.9	Malignant neoplasm of major salivary gland, unspecified
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

ICD-10	ICD-10 Description
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
C18.0	Malignant neoplasm of cecum
C18.2	Malignant neoplasm of ascending colon
C18.3	Malignant neoplasm of hepatic flexure
C18.4	Malignant neoplasm of transverse colon
C18.5	Malignant neoplasm of splenic flexure
C18.6	Malignant neoplasm of descending colon
C18.7	Malignant neoplasm of sigmoid colon
C18.8	Malignant neoplasm of overlapping sites of colon
C18.9	Malignant neoplasm of colon, unspecified
C19	Malignant neoplasm of rectosigmoid junction
C20	Malignant neoplasm of rectum
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, 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

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
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
C54.0	Malignant neoplasm of isthmus uteri
C54.1	Malignant neoplasm of endometrium
C54.2	Malignant neoplasm of myometrium
C54.3	Malignant neoplasm of fundus uteri
C54.8	Malignant neoplasm of overlapping sites of corpus uteri
C54.9	Malignant neoplasm of corpus uteri, unspecified
C55	Malignant neoplasm of uterus, part unspecified
C79.32	Secondary malignant neoplasm of cerebral meninges
C78.00	Secondary malignant neoplasm of unspecified lung
C78.01	Secondary malignant neoplasm of right lung
C78.02	Secondary malignant neoplasm of left lung
C78.6	Secondary malignant neoplasm of retroperitoneum and peritoneum
C78.7	Secondary malignant neoplasm of liver and intrahepatic bile duct
C79.31	Secondary malignant neoplasm of brain
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
Z85.01	Personal history of malignant neoplasm of esophagus

ICD-10	ICD-10 Description
Z85.028	Personal history of other malignant neoplasm of stomach
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.3	Personal history of malignant neoplasm of breast
Z85.42	Personal history of malignant neoplasm of other parts of uterus

Appendix 2 – Centers for Medicare and Medicaid Services (CMS)

The preceding information is intended for non-Medicare coverage determinations. Medicare coverage for outpatient (Part B) drugs is outlined in the Medicare Benefit Policy Manual (Pub. 100-2), Chapter 15, §50 Drugs and Biologicals. In addition, National Coverage Determinations (NCDs) and/or Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. Local Coverage Articles (LCAs) may also exist for claims payment purposes or to clarify benefit eligibility under Part B for drugs which may be self-administered. The following link may be used to search for NCD, LCD, or LCA documents: https://www.cms.gov/medicare-coverage-database/search.aspx. Additional indications, including any preceding information, may be applied at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA): N/A

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
E (1)	CA, HI, NV, AS, GU, CNMI	Noridian Healthcare Solutions, LLC
F (2 & 3)	AK, WA, OR, ID, ND, SD, MT, WY, UT, AZ	Noridian Healthcare Solutions, LLC
5	KS, NE, IA, MO	Wisconsin Physicians Service Insurance Corp
6	MN, WI, IL	National Government Services, Inc. (NGS)
H (4 & 7)	LA, AR, MS, TX, OK, CO, NM	Novitas Solutions, Inc.
8	MI, IN	Wisconsin Physicians Service Insurance Corp
N (9)	FL, PR, VI	First Coast Service Options, Inc.
J (10)	TN, GA, AL	Palmetto GBA
M (11)	NC, SC, WV, VA (excluding below)	Palmetto GBA
L (12)	DE, MD, PA, NJ, DC (includes Arlington & Fairfax counties and the city of Alexandria in VA)	Novitas Solutions, Inc.
K (13 & 14)	NY, CT, MA, RI, VT, ME, NH	National Government Services, Inc. (NGS)
15	KY, OH	CGS Administrators, LLC