

## Trastuzumab:

### Herceptin®; Ogivri®; Kanjinti™; Trazimera™; Herzuma®; Ontruzant® (Intravenous)

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#### I. Length of Authorization <sup>1</sup>

Coverage is provided for 6 months and may be renewed (unless otherwise specified).

- Neoadjuvant and adjuvant treatment in Breast Cancer may be authorized up to a maximum of fifty-two (52) weeks of treatment [18 cycles].

#### II. Dosing Limits

##### A. Quantity Limit (max daily dose) [NDC Unit]:

- 150 mg single-dose vial: 6 vials day 1, then 5 vials every 21 days thereafter
- 420 mg multiple-dose vial: 3 vials day 1, then 2 vials every 21 days thereafter

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

|  | Indication   | Load (1-time) | Load Billable Units (1-time) | Maint.  | Maint. Billable Units | Interval (Days) |
|--|--|---------------|------------------------------|---------|-----------------------|-----------------|
| Herceptin<br>(150 mg SDV)                    | Breast Cancer, Colorectal Cancer, Appendiceal Adenocarcinoma                             | 4 mg/kg       | 45                           | 2 mg/kg | 30                    | 7               |
|  |  | 8 mg/kg       | 90                           | 6 mg/kg | 75                    | 21              |
|  | Gastric, Esophageal, GEJ Cancer  | 6 mg/kg       | 75                           | 4 mg/kg | 45                    | 14              |
|  |  | 8 mg/kg       | 90                           | 6 mg/kg | 75                    | 21              |
|  | CNS mets from Breast Cancer, Uterine Cancer, Head and Neck Cancer, Hepatobiliary Cancers | 8 mg/kg       | 90                           | 6 mg/kg | 75                    | 21              |
| Leptomeningeal Metastases from Breast Cancer | N/A  | N/A           | 100 mg                       | 15      | 7                     |                 |

|   | Indication   | Load (1-time) | Load Billable Units (1-time) | Maint.  | Maint. Billable Units | Interval (Days) |
|---|--|---------------|------------------------------|---------|-----------------------|-----------------|
| Ogivri,<br>Kanjinti,<br>Trazimera,<br>Herzuma,<br>Ontruzant<br>(420 mg MDV) | Breast Cancer, Colorectal Cancer; Appendiceal Adenocarcinoma                             | 4 mg/kg       | 46                           | 2 mg/kg | 23                    | 7               |
|   |  | 8 mg/kg       | 92                           | 6 mg/kg | 69                    | 21              |
|   | Gastric, Esophageal, GEJ Cancer  | 6 mg/kg       | 69                           | 4 mg/kg | 46                    | 14              |
|   |  | 8 mg/kg       | 92                           | 6 mg/kg | 69                    | 21              |
|   | CNS mets from Breast Cancer, Uterine Cancer, Head and Neck Cancer, Hepatobiliary Cancers | 8 mg/kg       | 92                           | 6 mg/kg | 69                    | 21              |
| Leptomeningeal Metastases from Breast Cancer                                | N/A  | N/A           | 100 mg                       | 10      | 7                     |                 |

### III. Initial Approval Criteria <sup>1</sup>

Coverage is provided in the following conditions:

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

#### Universal Criteria <sup>1</sup>

- 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❖; **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 † ‡ <sup>1-8,10-16,35-38,43,44</sup>

- Used as adjuvant therapy; **AND**
  - Used in combination with a taxane-based regimen (e.g., docetaxel, paclitaxel, etc.) †; **OR**
  - Used as a single agent following chemotherapy; **OR**
  - Used in combination with pertuzumab for locally advanced, node positive, or inflammatory disease; **OR**
- Used as neoadjuvant or preoperative therapy; **AND**
  - Patient has locally advanced, node positive, 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 or metastatic disease OR inflammatory breast cancer with no response to preoperative systemic therapy; **AND**

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- Used as a single agent in patients who have received one or more prior chemotherapy regimens for metastatic disease †; **OR**
- Used as first-line therapy in combination with paclitaxel †; **OR**
- Used in combination with endocrine therapy (e.g., tamoxifen, fulvestrant, or aromatase inhibition with or without lapatinib) in patients with hormone-receptor positive disease; **AND**
  - Patient is post-menopausal; **OR**
  - Patient is pre-menopausal and is treated with ovarian ablation/suppression; **OR**
  - Patient is a male receiving concomitant suppression of testicular steroidogenesis; **OR**
- Used in combination with one of the following:
  - Pertuzumab and a taxane (e.g., docetaxel, paclitaxel) as first-line therapy
  - Capecitabine and tucatinib as second-line therapy and beyond
  - Cytotoxic chemotherapy as third-line therapy and beyond
  - Lapatinib (without cytotoxic therapy) as third-line therapy and beyond
  - Pertuzumab with or without cytotoxic therapy as subsequent therapy in patients previously treated with chemotherapy and trastuzumab (without pertuzumab)

#### Central Nervous System Cancer † <sup>7,18,29,30</sup>

- Patient has leptomeningeal metastases from breast cancer; **AND**
  - Trastuzumab will be administered intrathecally; **OR**
- Patient has brain metastases from breast cancer; **AND**
  - Used in combination with capecitabine and tucatinib; **AND**
  - Patient has previously been treated with at least one HER2-directed regimen; **AND**
    - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
    - Patient has recurrent limited brain metastases; **OR**
    - Patient has recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options; **OR**
    - Patient has relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options

#### Gastric, Esophageal, and Esophagogastric Junction Cancers † $\Phi$ <sup>1-7,17,32,33</sup>

- Patient has unresectable (or medically inoperable) locally advanced, recurrent, or metastatic adenocarcinoma; **AND**

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- Used as first-line therapy in combination with chemotherapy with or without pembrolizumab (*excluding use with anthracyclines or in combination with DCF [docetaxel, carboplatin, and fluorouracil]*)

#### **Uterine Cancer (Endometrial Carcinoma) ‡ 7,19,34**

- Used in combination with carboplatin and paclitaxel; **AND**
- Patient has advanced (stage III/IV) or recurrent uterine serous carcinoma

#### **Colorectal Cancer ‡ 7,9,31**

- Patient has RAS and BRAF wild-type (WT) disease; **AND**
- Used in combination with pertuzumab or lapatinib; **AND**
- Patient has not previously received HER2-directed therapy; **AND**
  - Used as subsequent therapy for progression of advanced or metastatic disease after at least one prior line of treatment in the advanced or metastatic disease setting; **OR**
  - Used as primary treatment for unresectable (or medically inoperable), locally advanced, or metastatic disease; **AND**
    - Patient is not appropriate for intensive therapy

#### **Appendiceal Adenocarcinoma – Colorectal Cancer ‡ 7,9**

- Patient has advanced or metastatic disease; **AND**
- Patient has RAS and BRAF wild-type (WT) disease; **AND**
- Used in combination with pertuzumab or lapatinib; **AND**
- Patient has not previously received HER2-targeted therapy; **AND**
  - Used as initial therapy if intensive therapy is not recommended; **OR**
  - Used as subsequent therapy

#### **Head and Neck Cancer ‡ 7,39-42**

- Patient has salivary gland tumors; **AND**
- Used as a single agent OR in combination with either docetaxel or pertuzumab; **AND**
- Used for one of the following:
  - Recurrent disease with distant metastases
  - Unresectable locoregional recurrence with prior radiation therapy (RT)
  - Recurrent unresectable second primary with prior RT

#### **Hepatobiliary Cancers ‡ 7,45,46**

- Patient has gallbladder cancer, extrahepatic cholangiocarcinoma, or intrahepatic cholangiocarcinoma; **AND**
- Used as subsequent treatment for progression on or after systemic treatment for unresectable or metastatic disease; **AND**

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- Used in combination with pertuzumab

| *HER2-positive overexpression criteria   |
|--|
| <b>Breast, CNS, Uterine, Head and Neck, and Hepatobiliary Cancer:</b> <sup>8,10</sup>  |
| <ul style="list-style-type: none"> <li>• Immunohistochemistry (IHC) assay 3+; <b>OR</b></li> <li>• Dual-probe in situ hybridization (ISH) assay HER2/CEP17 ratio <math>\geq 2.0</math> AND average HER2 copy number <math>\geq 4.0</math> signals/cell; <b>OR</b></li> <li>• Dual-probe in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:               <ul style="list-style-type: none"> <li>○ HER2/CEP17 ratio <math>\geq 2.0</math> AND average HER2 copy number <math>&lt; 4.0</math> signals/cell AND concurrent IHC 3+; <b>OR</b></li> <li>○ HER2/CEP17 ratio <math>&lt; 2.0</math> AND average HER2 copy number <math>\geq 6.0</math> signals/cell AND concurrent IHC 2+ or 3+; <b>OR</b></li> <li>○ HER2/CEP17 ratio <math>&lt; 2.0</math> AND average HER2 copy number <math>\geq 4.0</math> and <math>&lt; 6.0</math> signals/cell AND concurrent IHC 3+</li> </ul> </li> </ul> |
| <b>Gastric, Esophageal, and Esophagogastric Junction Cancer:</b> <sup>32,33,48</sup>   |
| <ul style="list-style-type: none"> <li>• Immunohistochemistry (IHC) assay 3+; <b>OR</b></li> <li>• Fluorescence in situ hybridization (FISH) or in situ hybridization (ISH) assay AND concurrent IHC indicating one of the following:               <ul style="list-style-type: none"> <li>○ HER2/CEP17 ratio <math>\geq 2.0</math> AND concurrent IHC 2+; <b>OR</b></li> <li>○ Average HER2 copy number <math>\geq 6.0</math> signals/cell AND concurrent IHC 2+</li> </ul> </li> </ul>   |
| <b>Colorectal Cancer and Appendiceal Adenocarcinoma:</b> <sup>9,31</sup>   |
| <ul style="list-style-type: none"> <li>• Immunohistochemistry (IHC) assay 3+; <b>OR</b></li> <li>• Fluorescence in situ hybridization (FISH) HER2/CEP17 ratio <math>\geq 2</math> AND concurrent IHC 2+; <b>OR</b></li> <li>• Next-generation sequencing (NGS) panel HER2 amplification</li> </ul>   |

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

† FDA Approved Indication(s); ‡ Compendia recommended Indication(s); Ⓞ Orphan Drug

#### IV. Renewal Criteria <sup>1</sup>

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**
- 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: cardiotoxicity (e.g., left ventricular dysfunction, cardiomyopathy, etc.), pulmonary toxicity (e.g., dyspnea, interstitial pneumonitis, etc.), severe or febrile neutropenia, infusion-related reactions, etc.; **AND**

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- 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  $\geq 16\%$  from pre-treatment baseline; **OR**
  - LVEF is below the institutional lower limits of normal, and has not had an absolute decrease of  $\geq 10\%$  from pre-treatment baseline; **AND**

### Breast Cancer (neoadjuvant and adjuvant therapy)

- Patient has not exceeded a maximum of fifty-two (52) weeks of treatment (total 18 cycles)

## V. Dosage/Administration <sup>1-9,18,19,29,31-33,40-42,45</sup>

| Indication  | Dose   |
|---|--|
| Breast Cancer   | <p><b><u>Neoadjuvant/Adjuvant Therapy</u></b></p> <p><b><u>Combination Therapy</u></b></p> <p>–Administer an initial dose of 4 mg/kg intravenously followed by 2 mg/kg intravenously weekly during chemotherapy for up to 18 weeks.</p> <p>–One week following the last weekly dose of trastuzumab, administer 6 mg/kg intravenously every three weeks.</p> <p><b>OR</b></p> <p>–Administer an initial dose of 4 mg/kg intravenously followed by 2 mg/kg intravenously weekly.</p> <p><b>OR</b></p> <p>–Administer an initial dose at 8 mg/kg intravenously followed by 6 mg/kg intravenously every three weeks.</p> <p><b><u>Single-Agent Therapy (following chemotherapy)</u></b></p> <p>–Administer an initial dose at 8 mg/kg intravenously, followed by subsequent doses at 6 mg/kg intravenously every three weeks.</p> <p><i>Note: Use for neoadjuvant and adjuvant treatment is limited to a total of 52 weeks of treatment (total of 18 cycles).</i></p> <p><b><u>Recurrent or Metastatic Disease (alone or in combination with chemotherapy)</u></b></p> <p>Loading dose: 4 mg/kg intravenously x 1 for every 7-day dosing schedule</p> <p>Maintenance dose: 2 mg/kg intravenously every 7 days</p> <p><b>OR</b></p> <p>Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule</p> <p>Maintenance dose: 6 mg/kg every 21 days</p> <p><i>Note: Treat until disease progression or intolerable toxicity.</i></p> |
| Gastric, Esophageal, and Esophagogastric Junction Cancers | <p>Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule</p> <p>Maintenance dose: 6 mg/kg intravenously every 21 days</p> <p><b>OR</b></p> <p>Loading dose: 6 mg/kg intravenously x 1 for every 14-day dosing schedule</p> <p>Maintenance dose: 4 mg/kg intravenously every 14 days</p> <p><i>Note: Treat until disease progression or intolerable toxicity.</i></p>  |

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|  |   |
|--|---|
| Colorectal Cancer & Appendiceal Adenocarcinoma | <p>Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule</p> <p>Maintenance dose: 6 mg/kg intravenously every 21 days</p> <p><b>OR</b></p> <p>Loading dose: 4 mg/kg intravenously x 1 for every 7-day dosing schedule</p> <p>Maintenance dose: 2 mg/kg intravenously every 7 days</p> <p><i>Note: Treat until disease progression or intolerable toxicity.</i></p> |
| Leptomeningeal Metastases from Breast Cancer   | <p>Escalating doses up to 100 mg intrathecally weekly*</p> <p><i>*Dosing is highly variable and should be individualized.</i></p> <p><i>Note: Treat until disease progression or intolerable toxicity.</i></p>  |
| All other indications                          | <p>Loading dose: 8 mg/kg intravenously x 1 for every 21-day dosing schedule</p> <p>Maintenance dose: 6 mg/kg intravenously every 21 days</p> <p><i>Note: Treat until disease progression or intolerable toxicity.</i></p>   |

## 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<br>(discontinued) | 50242-0333-xx<br>(discontinued) |
| Ogivri  | Q5114 | Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg    | 10 mg | 150 mg SDV                   | 67457-0991-xx                   |
|   |       |   |       | 420 mg MDV<br>(with diluent) | 67457-0847-xx                   |
|   |       |   |       | 420 mg MDV (no diluent)      | 67457-0845-xx                   |
| Kanjinti  | Q5117 | Injection, trastuzumab-anns, biosimilar, (Kanjinti), 10 mg  | 10 mg | 150 mg SDV                   | 55513-0141-xx                   |
|   |       |   |       | 420 mg MDV                   | 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                   |
| Ontruzant   | Q5112 | Injection, Trastuzumab-dttb, biosimilar, (Ontruzant), 10 mg | 10 mg | 150 mg SDV                   | 78206-0147-xx                   |
|   |       |   |       | 420 mg MDV                   | 78206-0148-xx                   |
| <p><u>Notes:</u></p> <ul style="list-style-type: none"> <li>Herceptin is only available as a single-dose vial; therefore, the JW modifier is allowed</li> <li>Ogivri, Kanjinti, Trazimera, Herzuma, &amp; 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</li> </ul> |       |   |       |                              |                                 |

## VII. References

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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                           |
| 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                                     |
| C18.1  | Malignant neoplasm of appendix                                  |

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| ICD-10  | ICD-10 Description  |
|---------|---|
| 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 large intestines             |
| 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      |
| 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   |

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| ICD-10  | ICD-10 Description  |
|---------|---|
| 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             |

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| ICD-10  | ICD-10 Description  |
|---------|---|
| 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                        |
| 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                                 |
| C79.32  | Secondary malignant neoplasm of cerebral meninges                     |
| 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                   |
| 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                      |

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

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 Determination (NCD), Local Coverage Articles (LCAs), and Local Coverage Determinations (LCDs) may exist and compliance with these policies is required where applicable. They can be found at: <https://www.cms.gov/medicare-coverage-database/search.aspx>. Additional indications may be covered at the discretion of the health plan.

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

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| <b>Jurisdiction(s):</b> N(9)  | <b>NCD/LCD Document (s):</b> A56660 |
| <a href="https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56660&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP">https://www.cms.gov/medicare-coverage-database/new-search/search-results.aspx?keyword=a56660&amp;areaId=all&amp;docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMD%2C6%2C3%2C5%2C1%2CF%2CP</a> |                                     |

| <b>Medicare Part B Administrative Contractor (MAC) Jurisdictions</b> |   |   |
|--|---|---|
| <b>Jurisdiction</b>  | <b>Applicable State/US Territory</b>  | <b>Contractor</b>                                 |
| 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 (WPS) |
| 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 (WPS) |
| N (9)  | FL, PR, VI  | First Coast Service Options, Inc.                 |
| J (10)   | TN, GA, AL  | Palmetto GBA, LLC                                 |
| M (11)   | NC, SC, WV, VA (excluding below)  | Palmetto GBA, LLC                                 |
| 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                           |

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