Trastuzumab:
Herceptin®; Ogivri®; Kanjinti®; Trazimera™; Herzuma®; Ontruzant®; Hercessi™
(Intravenous)

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

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

- Preoperative and adjuvant treatment in Breast Cancer may be authorized up to a maximum of fifty-two (52) weeks of treatment.

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]:

- Herceptin, Hercessi (150 mg SDV):
  - Gastric, Esophageal, and Esophagogastric Junction Cancer:
    - Load: 90 billable units x 1 dose
    - Maintenance: 75 billable units every 14 days
  - CNS Cancer: 300 billable units every 28 days
  - Breast Cancer, Colorectal Cancer & Appendiceal Adenocarcinoma, All other indications: 90 billable units every 21 days
- Ogivri, Kanjinti, Trazimera, Herzuma, Ontruzant (420 mg MDV):
  - Gastric, Esophageal, and Esophagogastric Junction Cancer:
    - Load: 92 billable units x 1 dose
    - Maintenance: 69 billable units every 14 days

- CNS Cancer: 276 billable units every 28 days
- Breast Cancer, Colorectal Cancer & Appendiceal Adenocarcinoma, All other indications: 92 billable units every 21 days

III. Initial Approval Criteria [1-7]

Coverage is provided in the following conditions:

- Patient must try and have an inadequate response, contraindication, or intolerance to Kanjinti, Ogivri, AND Trazimera; **OR**
- Patient is continuing treatment with a different trastuzumab product

Step therapy does not apply to MN residents with metastatic cancer per statute 62Q.1841. https://www.revisor.mn.gov/statutes/cite/62Q.1841

- 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❖; **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]

- Used as adjuvant 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 as a single agent; **OR**
    - Used in combination with pertuzumab; **OR**
- Used as 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 (local or regional) or metastatic disease OR inflammatory breast cancer; **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 †
  - Endocrine therapy (e.g., 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) ¥
  - Pertuzumab and a taxane (e.g., docetaxel, paclitaxel) as first-line therapy
  - Capecitabine and tucatinib as second-line therapy and beyond
  - Cytotoxic chemotherapy as fourth-line therapy and beyond
  - Lapatinib (without cytotoxic therapy) as fourth-line therapy and beyond
  - Pertuzumab with or without cytotoxic therapy as subsequent therapy in patients previously treated with chemotherapy and trastuzumab (without pertuzumab)

¥ 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; **AND**
    - Used as primary treatment in patients with good risk status (i.e., KPS ≥60, no major neurologic deficits, minimal systemic disease, or reasonable systemic treatment options); **OR**
    - Used as maintenance therapy; **OR**
- Patient has brain metastases from breast cancer; **AND**
  - Used in combination with one of the following:
    - Pertuzumab
    - Capecitabine and tucatinib in patients previously treated with at least one anti-HER2-based regimen; **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]

- Patient has adenocarcinoma; **AND**
  - Used as induction systemic therapy for relieving dysphagia (*applies to Esophageal and Esophagogastric Junction Cancers ONLY*); **AND**
    - Patient is medically fit and planned for esophagectomy with cT2, N0 (high-risk lesions: lymphovascular invasion, ≥ 3 cm, poorly differentiated), cT1b-cT2, N+ or cT3-cT4a, Any N disease; **AND**
    - Used in combination with chemotherapy; **OR**
  - Patient has early-stage disease***** with favorable histology *(applies to Gastric Cancer ONLY);* **AND**
    - Patient has completed an endoscopic resection; **AND**
      - Used in combination with chemotherapy; **OR**
      - Used in combination with pembrolizumab, fluoropyrimidine- and platinum-containing chemotherapy; **AND**
        - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖; **OR**
  - 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, fluoropyrimidine- and platinum-containing chemotherapy; **AND**
        - Tumor expresses PD-L1 (CPS ≥ 1) as determined by an FDA-approved or CLIA compliant test❖

****** *Endoscopic features suggestive of deep submucosal invasion include converging folds, irregular surface pattern, and ulceration in a large gastric mass*

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 OR carcinosarcoma; **AND**
  - Patient has stage III/IV disease; **OR**
  - Patient has recurrent disease and has not received prior trastuzumab therapy

Colorectal Cancer (CRC) ‡ [8,10,32]

- Patient has RAS and BRAF wild-type (WT) disease; **AND**

- Used in combination with pertuzumab, lapatinib, or tucatinib; **AND**
  - Used as initial treatment for unresectable metastatic disease and previous FOLFOX or CapeOX within the past 12 months; **AND**
    - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **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**
      - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
      - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**
        - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; **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 if resection is contraindicated following total neoadjuvant therapy; **AND**
      - Patient has proficient mismatch repair/microsatellite-stable (pMMR/MSS) disease; **OR**
      - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**
        - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy; **OR**
    - Used if resection is contraindicated following neoadjuvant/definitive immunotherapy; **AND**
      - Patient has deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H) disease; **OR**
  - Used as subsequent therapy for progression of advanced or metastatic disease; **AND**
    - Patient has not previously received HER2-directed therapy; **AND**
      - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
      - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**
        - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy

Appendiceal Adenocarcinoma – Colon Cancer ‡ [8,10]

- Patient has RAS and BRAF wild-type (WT) disease; **AND**
- Used in combination with pertuzumab, lapatinib, or tucatinib; **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 in one of the following:
  - Patient has mismatch repair proficient/microsatellite-stable (pMMR/MSS) disease; **OR**
  - Patient has mismatch repair deficient/microsatellite instability-high (dMMR/MSI-H) disease or polymerase epsilon/delta (POLE/POLD1) mutation; **AND**
    - Patient is not eligible for or has progressed on checkpoint inhibitor immunotherapy

Head and Neck Cancer ‡ [8,40-43]

- Patient has salivary gland tumors; **AND**
- Used as a single agent OR 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

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

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

❖ *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**
- 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; **AND**

Breast Cancer (preoperative and adjuvant therapy) [1-8]

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

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

Indication	Dose
Breast Cancer	**Preoperative or Adjuvant Therapy** In Combination With Chemotherapy Loading dose: 4 mg/kg intravenously x 1 for every 7-day dosing schedule Maintenance dose: 2 mg/kg intravenously every 7 days for up to 18 weeks. –One week following the last weekly dose of trastuzumab, administer 6 mg/kg intravenously every 21 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 Single-Agent Therapy (following chemotherapy) 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 preoperative and adjuvant treatment is limited to a total of 52 weeks of treatment.* **Recurrent, Unresectable, Metastatic Disease OR Inflammatory breast cancer (alone or in combination with chemotherapy)** 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	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 100 mg intrathecally weekly* **Dosing is highly variable and should be individualized.* **Limited or Extensive Brain Metastases from Breast Cancer** Combination Therapy with pertuzumab –Administer 6 mg/kg intravenously every 7 days 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
Ontruzant	Q5112	Injection, trastuzumab-dttb, biosimilar, (ontruzant), 10 mg	10 mg	150 mg SDV	78206-0147-xx
				420 mg MDV	78206-0148-xx
Hercessi	J9999	Not otherwise classified, antineoplastic	n/a	150 mg SDV	69448-0015-xx
Notes:					

Brand Name	HCPCS	HCPCS Description	1 BU	Vial Size & Type	NDCs
• Herceptin and Hercessi are only available as a single-dose vial; therefore, the JW modifier is allowed. • Ogivri, Kanjinti, Trazimera, Herzuma, & 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.					

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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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

ICD-10	ICD-10 Description
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
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		
Jurisdiction	**NCD/LCA/LCD Document (s)**	**Contractor**
N	A56660	First Coast Service Options, Inc.

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 (WPS)
6	MN, WI, IL	National Government Services, Inc. (NGS)

Medicare Part B Administrative Contractor (MAC) Jurisdictions		
Jurisdiction	**Applicable State/US Territory**	**Contractor**
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
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

Nondiscrimination & Language Access Policy

Discrimination is Against the Law. Aspirus Health Plan, Inc. complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex, (including sex characteristics, including intersex traits; pregnancy or related conditions; sexual orientation, gender identity and sex stereotypes), consistent with the scope of sex discrimination described at 45 CFR § 92.101(a)(2). Aspirus Health Plan, Inc. does not exclude people or treat them less favorably because of race, color, national origin, age, disability, or sex.

Aspirus Health Plan, Inc.:
Provides people with disabilities reasonable modifications and free appropriate auxiliary aids and services to communicate effectively with us, such as:

- Qualified sign language interpreters.
- Written information in other formats (large print, audio, accessible electronic formats, other formats).

Provides free language assistance services to people whose primary language is not English, which may include:

- Qualified interpreters.
- Information written in other languages.

If *you* need reasonable modifications, appropriate auxiliary aids and services, or language assistance services, contact the Nondiscrimination Grievance Coordinator at the address, phone number, fax number, or email address below.

If *you* believe that Aspirus Health Plan, Inc. has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, or sex, *you* can file a *grievance* with:

Nondiscrimination Grievance Coordinator
Aspirus Health Plan, Inc.
PO Box 1890
Southampton, PA 18966-9998
Phone: 1-866-631-5404 (TTY: 711)
Fax: 763-847-4010
Email: customerservice@aspirushealthplan.com

You can file a *grievance* in person or by mail, fax, or email. If *you* need help filing a *grievance*, the Nondiscrimination Grievance Coordinator is available to help *you*.

You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at:

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1.800.368.1019, 800.537.7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html. This notice is available at Aspirus Health Plan, Inc.'s website: https://aspirushealthplan.com/webdocs/70021-AHP-NonDiscrim_Lang-Assist-Notice.pdf.

Language Assistance Services

Albanian: KUJDES: Nëse flitni shqip, për ju ka në dispozicion shërbime të asistencës gjuhësore, pa pagesë.Telefononi në 1-800-332-6501 (TTY: 711).

Arabic تنبيه: إذا كنت تتحدث اللغة العربية، فإن خدمات المساعدة اللغوية متاحة لك مجاناً. اتصل بن اعلى رقم الهاتف1-800-332-6501(رقم هاتف الصم والبك : 711)

French: ATTENTION: Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1-800-332-6501 (ATS: 711).

German: ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zurVerfügung. Rufnummer: 1-800-332-6501 (TTY: 711).

Hindi: _यान द_: य_द आप ि हंदी बोलते ह_ तो आपके ि लए मु_त म_ भाषा सहायता सेवाएं उपल_ध ह_।1-800-332-6501 (TTY: 711) पर कॉल कर_।

Hmong: LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1-800-332-6501 (TTY: 711).

Korean: 주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다.1-800-332-6501 (TTY: 711)번으로 전화해 주십시오.

Polish: UWAGA: Jeżeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer1-800-332-6501 (TTY: 711).

Russian: ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода.Звоните 1-800-332-6501 (телетайп: 711).

Spanish: ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al1-800-332-6501 (TTY: 711).

Tagalog: PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nangwalang bayad. Tumawag sa 1-800-332-6501 (TTY: 711).

Traditional Chinese: 注意：如果您使用繁體中文， 您可以免費獲得語言援助服務。請 致電 1-800-332-6501 (TTY: 711)

Vietnamese: CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1-800-332-6501 (TTY: 711).

Pennsylvania Dutch: Wann du Deitsch (Pennsylvania German / Dutch) schwetzscht, kannscht du mitaus Koschte ebbergricke, ass dihr helft mit die englisch Schprooch. Ruf selli Nummer uff: Call 1-800-332-6501 (TTY: 711).

Lao: ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ,ໂດຍບໍ່ເສັງຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1-800-332-6501 (TTY: 711).