

## Retevmo<sup>®</sup> (selpercatinib) (Oral)

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### I. Length of Authorization

Coverage will be provided for 6 months and may be renewed.

### II. Dosing Limits

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

- Retevmo 40 mg capsules: 2 capsules per day
- Retevmo 80 mg capsules: 2 capsules per day
- Retevmo 40 mg tablets: 2 tablets per day
- Retevmo 80 mg tablets: 2 tablets per day
- Retevmo 120 mg tablets: 2 tablets per day
- Retevmo 160 mg tablets: 2 tablets per day

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

- 320 mg per day

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

Coverage is provided in the following conditions:

- Patient is at least 2 years of age (unless otherwise specified); **AND**

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

- Used as a single agent; **AND**
- Patient does not have uncontrolled hypertension; **AND**
- Patient must not have had major surgery within the preceding 14 days or have a surgical wound that has not fully healed; **AND**
- Therapy will not be used concomitantly with other RET-type targeted therapies (i.e., cabozantinib, vandetanib, pralsetinib, etc.); **AND**
- Patient will avoid concomitant therapy with all of the following:
  - Coadministration with acid-reducing agents (e.g., proton pump inhibitors, histamine H<sub>2</sub>-receptor antagonists, and antacids), or if acid-reduction therapy is required, it will be administered at staggered administration times; **OR**

- Coadministration with strong or moderate CYP3A inhibitors (e.g., diltiazem, fluconazole, verapamil, itraconazole, etc.), or if therapy is unavoidable, the patient will be monitored closely for adverse reaction and/or dose modifications will be implemented; **OR**
- Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, bosentan, efavirenz, etc.); **AND**

### Non-Small Cell Lung Cancer (NSCLC) † ‡ ◊<sup>1-3,7</sup>

- Patient is at least 18 years of age; **AND**
- Patient has RET gene fusion/rearrangement positive disease as detected by an FDA-approved or CLIA compliant test ◊; **AND**
- Patient has recurrent, advanced, or metastatic disease (*excluding locoregional recurrence or symptomatic local disease without evidence of disseminated disease*) or mediastinal lymph node recurrence with prior radiation therapy

### Thyroid Cancer † ‡ ◊<sup>1,2,4,6</sup>

- Patient has RET gene fusion positive follicular, oncocytic, or papillary carcinoma as detected by an FDA-approved or CLIA compliant test ◊; **AND**
  - Patient has metastatic, advanced, or unresectable locoregional recurrent or persistent disease; **AND**
  - Patient is not amenable to RAI therapy; **OR**
- Patient has RET-mutation positive medullary thyroid cancer (MTC) as detected by an FDA-approved or CLIA compliant test ◊; **AND**
  - Patient has symptomatic or progressive disease; **OR**
  - Patient has advanced or metastatic disease; **OR**
- Patient has RET gene fusion positive anaplastic carcinoma as detected by an FDA-approved or CLIA compliant test ◊; **AND**
  - Used as neoadjuvant therapy for borderline resectable locoregional disease; **OR**
  - Used as first- or second-line therapy for metastatic disease

### RET Fusion-Positive Solid Tumors † ‡

- Patient has RET gene fusion positive solid tumors as detected by an FDA-approved or CLIA compliant test ◊; **AND**
- Patient has, but is not limited to\*, one of the following tumor types:
  - Breast Cancer<sup>2,10</sup>
    - Patient has recurrent unresectable (local or regional) disease, locally advanced or metastatic disease OR inflammatory disease with no response to preoperative systemic therapy; **AND**
    - Patient has no satisfactory alternative treatments or disease has progressed following treatment

- Central Nervous System (CNS) Cancers <sup>2,11</sup>
  - Patient has brain metastases from RET gene-fusion positive non-small cell lung cancer; **AND**
    - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
    - Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options; **OR**
    - Patient has recurrent limited brain metastases; **OR**
    - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options
- Cervical Cancer <sup>2</sup>
  - Used as subsequent therapy for recurrent or metastatic disease
- Colorectal Adenocarcinoma <sup>2</sup>
  - Patient has locally advanced or metastatic disease that has progressed on or following prior systemic therapy; **OR**
  - Patient has no satisfactory alternative treatment options
- Appendiceal Adenocarcinoma <sup>2</sup>
  - Used as subsequent therapy for progression of advanced or metastatic disease; **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
- Gastric Adenocarcinoma OR Esophageal/Esophagogastric Junction (GEJ) Adenocarcinoma/Squamous Cell Carcinoma <sup>2,10</sup>
  - Used palliatively as subsequent therapy; **AND**
  - Patient has unresectable (or is not a surgical candidate) locally advanced, recurrent or metastatic disease
- Head and Neck Cancer <sup>2,10</sup>
  - Patient has salivary gland tumors; **AND**
  - Patient has recurrent disease with one of the following:
    - Distant metastases; **OR**
    - Unresectable locoregional recurrence with prior radiation therapy (RT); **OR**
    - Unresectable second primary with prior RT
- Biliary Tract Cancers <sup>1,2</sup>

- Intra-/Extra-Hepatic cholangiocarcinoma; **AND**
  - Used as subsequent treatment for progression on or after systemic treatment for unresectable, resected gross residual (R2), or metastatic disease; **OR**
- Gallbladder cancer; **AND**
  - Used as neoadjuvant therapy for resectable locoregionally advanced disease; **AND**
    - Patient has incidental finding of suspicious mass during surgery where hepatobiliary surgery expertise is unavailable; **OR**
    - Patient has incidental finding on pathologic review (cystic duct node positive); **OR**
    - Patient has mass on imaging
- Histiocytic Neoplasms <sup>2,8</sup>
  - Patient has one of the following sub-types of disease:
    - Langerhans Cell Histiocytosis (LCH); **AND**
      - Used for multisystem disease with symptomatic or impending organ dysfunction or critical organ involvement; **OR**
      - Used for single-system lung LCH; **OR**
      - Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate; **OR**
      - Patient has CNS lesions; **OR**
      - Used for relapsed/refractory disease; **OR**
    - Erdheim-Chester Disease; **AND**
      - Patient has symptomatic disease; **OR**
      - Used for relapsed or refractory disease; **OR**
    - Rosai-Dorfman Disease; **AND**
      - Patient has symptomatic disease that is multifocal or unresectable unifocal; **OR**
      - Used for relapsed or refractory disease
- Neuroendocrine Tumors (Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm) <sup>2,10</sup>
  - Patient has locoregional unresectable or metastatic disease; **AND**
  - Patient progressed following prior treatment or has no satisfactory alternative treatment options
- Occult Primary/Cancer of Unknown Primary (CUP) <sup>1,2</sup>
  - Patient has disease that has progressed on or following prior systemic treatment or patient has no satisfactory alternative treatment options; **AND**

- Patient has adenocarcinoma or carcinoma not otherwise specified AND one of the following:
  - Axillary involvement in those with a prostate or post-prostatectomy if clinically indicated; **OR**
  - Lung nodules or breast marker-negative pleural effusion; **OR**
  - Resectable liver disease; **OR**
  - Peritoneal mass or ascites with non-ovarian histology; **OR**
  - Retroperitoneal mass of non-germ cell histology in selected patients; **OR**
  - Unresectable liver disease or disseminated metastases
- Ovarian Cancer (Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer) <sup>2</sup>
  - Patient has recurrent or persistent Grade 1 Endometrioid Carcinoma, Carcinosarcoma (Malignant Mixed Müllerian Tumors), Mucinous Carcinoma of the Ovary, Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer, or Clear Cell Carcinoma of the Ovary; **AND**
    - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); **OR**
  - Patient has recurrent Low-Grade Serous Carcinoma
- Pancreatic Adenocarcinoma <sup>2,10</sup>
  - Used for locally advanced, metastatic, progressive or recurrent disease
- Small Bowel Adenocarcinoma <sup>2,10</sup>
  - Used as subsequent therapy for advanced or metastatic disease
- Soft Tissue Sarcoma <sup>2,10</sup>
  - Used as first-line therapy for one of the following:
    - Advanced or metastatic pleomorphic rhabdomyosarcoma; **OR**
    - Advanced, unresectable, recurrent, or metastatic disease of the Extremity/Body Wall/Head-Neck **¥**; **OR**
    - Advanced, unresectable, or metastatic disease or post-operatively for sarcoma of the retroperitoneal or intra-abdominal area<sup>§</sup>; **OR**
  - Used as an alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable localized disease of the retroperitoneal or intra-abdominal area<sup>§</sup>; **OR**
  - Used as subsequent therapy for locally advanced or metastatic disease that has progressed on or following prior systemic treatment or patient has no satisfactory alternative treatment options

*¥ For atypical lipomatous tumor/well-differentiated liposarcoma (ALT/WDLs) of the extremity, abdominal wall, trunk that was initially diagnosed as ALT and shows evidence of de-differentiation, treat as other soft tissue sarcomas.*

*§ Treat well-differentiated liposarcoma (WDLs-retroperitoneum, paratesticular) with or without evidence of de-differentiation as other soft tissue sarcomas*

- Ampullary Adenocarcinoma <sup>2</sup>

- Used as first-line therapy for unresectable localized disease or metastatic disease; **OR**
- Used as subsequent therapy for disease progression
- Vaginal Cancer <sup>2</sup>
  - Patient has squamous cell carcinoma or adenocarcinoma; **AND**
  - Used as subsequent therapy for recurrent, or metastatic disease

*\*Note: Solid tumors not listed, that are RET-fusion positive, will be reviewed on a case-by-case basis and considered medically necessary when all other relevant medication and indication specific criteria are met.*

❖ *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 can be renewed based on 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: severe hepatotoxicity, severe hypersensitivity, QT interval prolongation, impaired wound healing, severe or life-threatening hemorrhagic events, uncontrolled hypertension, tumor lysis syndrome, interstitial lung disease/pneumonitis, hypothyroidism, slipped capital femoral epiphysis/slipped upper femoral epiphysis (in pediatric patients), etc.

#### V. Dosage/Administration <sup>1,4,9,11</sup>

Indication	Dose
All Indications	Administer (capsules or tablets) orally twice daily, until disease progression or unacceptable toxicity. <ul style="list-style-type: none"> <li>• Adult and adolescent patients ≥ 12 years of age based on body weight:               <ul style="list-style-type: none"> <li>○ &lt; 50 kg: 120 mg twice daily</li> <li>○ ≥ 50 kg: 160 mg twice daily</li> </ul> </li> <li>• Pediatric patients 2 to &lt; 12 years of age based on body surface area:               <ul style="list-style-type: none"> <li>○ 0.33 to 0.65 m<sup>2</sup>: 40 mg three times daily</li> <li>○ 0.66 to 1.08 m<sup>2</sup>: 80 mg twice daily</li> <li>○ 1.09 to 1.52 m<sup>2</sup>: 120mg twice daily</li> <li>○ ≥1.53 m<sup>2</sup>: 160 mg twice daily</li> </ul> </li> <li>• Dosing pediatric patients with body surface area less than 0.33 m<sup>2</sup> is not recommended</li> <li>• <b>Note:</b> Dosing for use in NSCLC only applies to patients who are at least 18 years of age.</li> </ul>

## VI. Billing Code/Availability Information

### HCPCS Code(s):

- J8999 – Prescription drug, oral, chemotherapeutic, nos
- C9399 – Unclassified drugs or biologicals (*for hospital outpatient use ONLY*)

### NDC(s):

- Retevmo 40 mg capsules: 00002-3977-xx
- Retevmo 80 mg capsules: 00002-2980-xx
- Retevmo 40 mg tablets: 00002-5340-xx
- Retevmo 80 mg tablets: 00002-6082-xx
- Retevmo 120 mg tablets: 00002-6120-xx
- Retevmo 160 mg tablets: 00002-5562-xx

## VII. References

1. Retevmo [package insert]. Indianapolis, IN; Lilly USA, LLC., May 2024. Accessed May 2024.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for selpercatinib. National Comprehensive Cancer Network, 2024. 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 May 2024.
3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer Version 5.2024. National Comprehensive Cancer Network, 2024. 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 Guidelines, go online to NCCN.org. Accessed May 2024.
4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Thyroid Carcinomas Version 2.2024. National Comprehensive Cancer Network, 2024. 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 Guidelines, go online to NCCN.org. Accessed May 2024.
5. ClinicalTrials.gov [Internet]. Bethesda (MD): National Library of Medicine (US). Date: 5/17/17. Identifier NCT03157128: A Phase 1/2 Study of Oral LOXO-292 in Patients With Advanced Solid Tumors, Including RET Fusion-Positive Solid Tumors, Medullary Thyroid Cancer, and Other Tumors With RET Activation (LIBRETTO-001); [Accessed 5/12/20]; [about 4 screens]. Available from: <https://clinicaltrials.gov/ct2/show/NCT03157128?term=NCT03157128&draw=2&rank=1>.
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8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Histiocytic Neoplasms 1.2004. National Comprehensive Cancer Network, 2024. 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 Guidelines, go online to NCCN.org. Accessed May 2024.
9. Durham BH, Lopez Rodrigo E, Picarsic J, et al. Activating mutations in CSF1R and additional receptor tyrosine kinases in histiocytic neoplasms. *Nat Med*. 2019 Dec;25(12):1839-1842. doi: 10.1038/s41591-019-0653-6.
10. Subbiah V, Wolf J, Konda B, et al. Tumour-agnostic efficacy and safety of selpercatinib in patients with RET fusion-positive solid tumours other than lung or thyroid tumours (LIBRETTO-001): a phase 1/2, open-label, basket trial. *Lancet Oncol*. 2022 Sep 12:S1470-2045(22)00541-1. doi: 10.1016/S1470-2045(22)00541-1.
11. Subbiah V, Gainor J, Oxnard G, et al. Intracranial Efficacy of Selpercatinib in RET Fusion-Positive Non-Small Cell Lung Cancers on the LIBRETTO-001 Trial. *Clin Cancer Res*. 2021 Aug 1;27(15):4160-4167. doi: 10.1158/1078-0432.CCR-21-0800. Epub 2021 Jun 4.
12. Morganstern DA, Mascarenhas L, Campbell M, et al. Oral selpercatinib in pediatric patients (pts) with advanced RET-altered solid or primary CNS tumors: Preliminary results from the phase 1/2 LIBRETTO-121 trial.. *JCO* 39, 10009-10009(2021). DOI:10.1200/JCO.2021.39.15\_suppl.10009.

## 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 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



ICD-10	ICD-10 Description
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
C17.0	Malignant neoplasm duodenum
C17.1	Malignant neoplasm jejunum
C17.2	Malignant neoplasm ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestines
C17.9	Malignant neoplasm of small intestine, 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
C22.1	Intrahepatic bile duct carcinoma
C23	Malignant neoplasm of gallbladder
C24.0	Malignant neoplasm of extrahepatic bile duct
C24.1	Malignant neoplasm of ampulla of Vater
C24.8	Malignant neoplasm of overlapping sites of biliary tract
C24.9	Malignant neoplasm of biliary tract, unspecified
C25.0	Malignant neoplasm of head of pancreas
C25.1	Malignant neoplasm of body of the pancreas
C25.2	Malignant neoplasm of tail of pancreas
C25.3	Malignant neoplasm of pancreatic duct
C25.7	Malignant neoplasm of other parts of pancreas
C25.8	Malignant neoplasm of overlapping sites of pancreas
C25.9	Malignant neoplasm of pancreas, unspecified
C33	Malignant neoplasm of trachea

ICD-10	ICD-10 Description
C34.00	Malignant neoplasm of unspecified main bronchus
C34.01	Malignant neoplasm of right main bronchus
C34.02	Malignant neoplasm of left main bronchus
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung
C34.2	Malignant neoplasm of middle lobe, bronchus or lung
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C47.0	Malignant neoplasm of peripheral nerves of head, face and neck
C47.10	Malignant neoplasm of peripheral nerves of unspecified upper limb, including shoulder
C47.11	Malignant neoplasm of peripheral nerves of right upper limb, including shoulder
C47.12	Malignant neoplasm of peripheral nerves of left upper limb, including shoulder
C47.20	Malignant neoplasm of peripheral nerves of unspecified lower limb, including hip
C47.21	Malignant neoplasm of peripheral nerves of right lower limb, including hip
C47.22	Malignant neoplasm of peripheral nerves of left lower limb, including hip
C47.3	Malignant neoplasm of peripheral nerves of thorax
C47.4	Malignant neoplasm of peripheral nerves of abdomen
C47.5	Malignant neoplasm of peripheral nerves of pelvis
C47.6	Malignant neoplasm of peripheral nerves of trunk, unspecified
C47.8	Malignant neoplasm of overlapping sites of peripheral nerves and autonomic nervous
C47.9	Malignant neoplasm of peripheral nerves and autonomic nervous system, unspecified
C48.0	Malignant neoplasm of retroperitoneum
C48.1	Malignant neoplasm of specified parts of peritoneum
C48.2	Malignant neoplasm of peritoneum, unspecified
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb including shoulder
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder

ICD-10	ICD-10 Description
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip
C49.3	Malignant neoplasm of connective and soft tissue of thorax
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, 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

ICD-10	ICD-10 Description
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast
C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
C52	Malignant neoplasm of vagina
C53.0	Malignant neoplasm of endocervix
C53.1	Malignant neoplasm of exocervix
C53.8	Malignant neoplasm of overlapping sites of cervix uteri
C53.9	Malignant neoplasm of cervix uteri, unspecified
C56.1	Malignant neoplasm of right ovary
C56.2	Malignant neoplasm of left ovary
C56.3	Malignant neoplasm of bilateral ovaries
C56.9	Malignant neoplasm of unspecified ovary
C57.00	Malignant neoplasm of unspecified fallopian tube
C57.01	Malignant neoplasm of right fallopian tube

ICD-10	ICD-10 Description
C57.02	Malignant neoplasm of left fallopian tube
C57.10	Malignant neoplasm of unspecified broad ligament
C57.11	Malignant neoplasm of right broad ligament
C57.12	Malignant neoplasm of left broad ligament
C57.20	Malignant neoplasm of unspecified round ligament
C57.21	Malignant neoplasm of right round ligament
C57.22	Malignant neoplasm of left round ligament
C57.3	Malignant neoplasm of parametrium
C57.4	Malignant neoplasm of uterine adnexa, unspecified
C57.7	Malignant neoplasm of other specified female genital organs
C57.8	Malignant neoplasm of overlapping sites of female genital organs
C57.9	Malignant neoplasm of female genital organ, unspecified
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
C7B.8	Other secondary neuroendocrine tumors
C73	Malignant neoplasm of thyroid gland
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
C80.0	Disseminated malignant neoplasm, unspecified
C80.1	Malignant (primary) neoplasm, unspecified
C96.0	Multifocal and multisystemic (disseminated) Langerhans-cell histiocytosis
C96.5	Multifocal and unisystemic Langerhans-cell histiocytosis
C96.6	Unifocal Langerhans-cell histiocytosis
C96.9	Malignant neoplasm of lymphoid, hematopoietic and related tissue, unspecified
C96.Z	Other specified malignant neoplasms of lymphoid, hematopoietic and related tissue
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
D76.3	Other histiocytosis syndromes
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

ICD-10	ICD-10 Description
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.07	Personal history of malignant neoplasm of pancreas
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z85.831	Personal history of malignant neoplasm of soft tissue
Z85.850	Personal history of malignant neoplasm of thyroid
Z85.858	Personal history of malignant neoplasm of other endocrine glands

## 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 (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
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