



Retevmo® (selpercatinib) (Oral)

Document Number: IC-0537

Last Review Date: 05/04/2023 Date of Origin: 6/02/2020

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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: 4 capsules per day

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

• 320 mg per day

III. Initial Approval Criteria ¹

Coverage is provided in the following conditions:

Patient is at least 18 years of age (unless otherwise specified); AND

Universal Criteria 1

- 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.)
- Patient will avoid concomitant therapy with all of the following:
 - Coadministration with acid-reducing agents, 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 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



o Coadministration with strong and moderate CYP3A inducers (e.g., rifampin, bosentan, efavirenz, etc.); **AND**

Non-Small Cell Lung Cancer (NSCLC) † ‡ Φ 1-3,7

- Patient has RET gene fusion/rearrangement positive disease as detected by an FDAapproved 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 † ‡ Φ 1,2,4,6

- Patient has RET gene fusion positive follicular, oncocytic, or papillary carcinoma as detected by an FDA-approved or CLIA compliant test*; AND
 - o Patient is at least 12 years of age; AND
 - Patient has metastatic, advanced, or unresectable locoregional recurrent or persistent disease; AND
 - Patient is radioactive iodine (RAI) therapy refractory or is not amenable to RAI therapy; OR
- Patient has RET-mutation positive medullary thyroid cancer (MTC) as detected by an FDAapproved or CLIA compliant test*; AND
 - o Patient is at least 12 years of age; 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
- Used as a single agent; AND
- Patient has, but is not limited to*, one of the following tumor types:
 - o Breast Cancer 2,10
 - Patient has no satisfactory alternative treatments or disease has progressed following treatment; AND
 - Patient has recurrent unresectable (local or regional) or stage IV (M1) disease; OR
 - Patient has not responded to preoperative systemic therapy



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- o Central Nervous System (CNS) Cancers ^{2,11}
 - 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
- o Cervical Cancer ²
 - Used as subsequent therapy for recurrent or metastatic disease
- o Colorectal Adenocarcinoma ²
 - Used as subsequent therapy for progression of metastatic disease
- o <u>Gastric Adenocarcinoma OR Esophageal/Esophagogastric Junction (GEJ)</u> Adenocarcinoma/Squamous Cell Carcinoma ^{2,10}
 - Used palliatively as subsequent therapy; AND
 - Patient has unresectable (or is not a surgical candidate) locally advanced, recurrent or metastatic disease
- o Head and Neck Cancer 2,10
 - Patient has salivary gland tumors; AND
 - Used for one of the following:
 - > Recurrent disease with distant metastases; **OR**
 - Unresectable locoregional recurrence or second primary with prior radiation therapy (RT)
- o Hepatobiliary Cancer ²
 - Used as subsequent treatment for progressive disease; AND
 - Patient has cholangiocarcinoma (Intra/Extra hepatic); AND
 - ➤ Patient has unresectable or metastatic disease; **OR**
 - Patient has hepatocellular carcinoma; AND
 - ➤ Patient has unresectable disease and is not a transplant candidate; **OR**
 - ➤ Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; **OR**
 - > Patient has metastatic disease or extensive liver tumor burden
- o <u>Histiocytic Neoplasms ²</u>
 - 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**
- ➤ Used for single-system lung LCH; **OR**
- ➤ Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate and more than 2 lesions; **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)^{2,10}
 - Patient has locoregional unresectable or metastatic disease; AND
 - Patient progressed following prior treatment and has no satisfactory alternative treatment options
- o Occult Primary/Cancer of Unknown Primary (CUP)^{2,10}
 - Patient has adenocarcinoma or carcinoma not otherwise specified; AND
 - Patient has 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)
 - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without evidence of radiographic disease);
 - Patient has persistent, relapsed, or recurrent disease
- o Pancreatic Adenocarcinoma 2,10
 - Used as subsequent therapy for locally advanced, metastatic, progressive or recurrent disease



- o Small Bowel Adenocarcinoma 2,10
 - Used as subsequent therapy for metastatic disease
- o Soft Tissue Sarcoma 2,10
 - 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; OR
 - Used as an alternative systemic therapy for unresectable or progressive disease after initial therapy for unresectable or stage IV for sarcoma of the retroperitoneal or intra-abdominal area

- ♦ 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

Coverage can be renewed based on the following criteria:

- Patient continues to meet 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, etc.

V. Dosage/Administration 1,9,11

| Indication | Dose | |
|-----------------|--|--|
| All Indications | Administer orally twice daily, until disease progression or unacceptable toxicity. | |
| | • Weight < 50 kg: 120 mg per dose | |
| | • Weight $\geq 50 \text{ kg}$: 160 mg per dose | |

VI. Billing Code/Availability Information

HCPCS Code(s):

• J8999 – Prescription drug, oral, chemotherapeutic, nos



^{*}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.

• 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

VII. References

- 1. Retevmo [package insert]. Indianapolis, IN; Lilly USA, LLC., September 2022. Accessed April 2023.
- 2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) for selpercatinib. National Comprehensive Cancer Network, 20223. 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 April 2023.
- 3. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Non-Small Cell Lung Cancer Version 2.2023. National Comprehensive Cancer Network, 2023. 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. AccessedApril 2023.
- 4. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Thyroid Carcinomas Version 1.2023. National Comprehensive Cancer Network, 2023. 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 April 2023.
- 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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- 7. Drilon A, Oxnard GR, Tan DSW, et al. Efficacy of Selpercatinib in RET Fusion-Positive Non-Small-Cell Lung Cancer. N Engl J Med. 2020 Aug 27;383(9):813-824. doi: 10.1056/NEJMoa2005653.
- 8. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Histiocytic Neoplasms 1.2002.2021. National Comprehensive Cancer Network, 2022. 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 April 2023.



- 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.

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 | | |
| 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 | | |

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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 | |
| 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 | |
| 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 | |
| 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 | |



| ICD-10 | ICD-10 Description | |
|---------|---|--|
| 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 | |
| C47.4 | Malignant neoplasm of peripheral nerves of abdomen | |
| C47.5 | Malignant neoplasm of peripheral nerves of pelvis | |
| 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 | |
| C47.6 | 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 | |
| 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 | |



| ICD-10 | ICD-10 Description | |
|---------|---|--|
| C50.029 | Malignant neoplasm of nipple and areola, unspecified female breast | |
| C50.111 | Malignant neoplasm of central portion of right female breast | |
| C50.112 | Malignant neoplasm of central portion of left female breast | |
| C50.119 | Malignant neoplasm of central portion of unspecified female breast | |
| C50.121 | Malignant neoplasm of central portion of right male breast | |
| C50.122 | Malignant neoplasm of central portion of left male breast | |
| C50.129 | Malignant neoplasm of central portion of unspecified male breast | |
| C50.211 | Malignant neoplasm of upper-inner quadrant of right female breast | |
| C50.212 | Malignant neoplasm of upper-inner quadrant of left female breast | |
| C50.219 | Malignant neoplasm of upper-inner quadrant of unspecified female breast | |
| C50.221 | Malignant neoplasm of upper-inner quadrant of right male breast | |
| C50.222 | Malignant neoplasm of upper-inner quadrant of left male breast | |
| C50.229 | Malignant neoplasm of upper-inner quadrant of unspecified male breast | |
| C50.311 | Malignant neoplasm of lower-inner quadrant of right female breast | |
| C50.312 | Malignant neoplasm of lower-inner quadrant of left female breast | |
| C50.319 | Malignant neoplasm of lower-inner quadrant of unspecified female breast | |
| C50.321 | Malignant neoplasm of lower-inner quadrant of right male breast | |
| C50.322 | Malignant neoplasm of lower-inner quadrant of left male breast | |
| C50.329 | Malignant neoplasm of lower-inner quadrant of unspecified male breast | |
| C50.411 | Malignant neoplasm of upper-outer quadrant of right female breast | |
| C50.412 | Malignant neoplasm of upper-outer quadrant of left female breast | |
| C50.419 | Malignant neoplasm of upper-outer quadrant of unspecified female breast | |
| C50.421 | Malignant neoplasm of upper-outer quadrant of right male breast | |
| C50.422 | Malignant neoplasm of upper-outer quadrant of left male breast | |
| C50.429 | Malignant neoplasm of upper-outer quadrant of unspecified male breast | |
| C50.511 | Malignant neoplasm of lower-outer quadrant of right female breast | |
| C50.512 | Malignant neoplasm of lower-outer quadrant of left female breast | |
| C50.519 | Malignant neoplasm of lower-outer quadrant of unspecified female breast | |
| C50.521 | Malignant neoplasm of lower-outer quadrant of right male breast | |
| C50.522 | Malignant neoplasm of lower-outer quadrant of left male breast | |
| C50.529 | Malignant neoplasm of lower-outer quadrant of unspecified male breast | |
| C50.611 | Malignant neoplasm of axillary tail of right female breast | |
| C50.612 | Malignant neoplasm of axillary tail of left female breast | |
| C50.619 | Malignant neoplasm of axillary tail of unspecified female breast | |
| C50.621 | Malignant neoplasm of axillary tail of right male breast | |
| C50.622 | Malignant neoplasm of axillary tail of left male breast | |
| C50.629 | Malignant neoplasm of axillary tail of unspecified male breast | |



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



| ICD-10 | ICD-10 Description | | |
|---------|---|--|--|
| 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 | | |
| C96.2 | Malignant mast cell neoplasm | | |
| 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 | | |
| Z85.068 | Personal history of other malignant neoplasm of small intestine | | |
| Z85.07 | Personal history of malignant neoplasm of pancreas | | |
| Z85.118 | Personal history of other malignant neoplasm of bronchus and lung | | |
| Z85.43 | Personal history of malignant neoplasm of ovary | | |
| Z85.831 | Personal history of malignant neoplasm of soft tissue | | |
| Z85.858 | Personal history of malignant neoplasm of other endocrine glands | | |

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 Determinations (LCDs), and Local Coverage Article (LCAs) 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/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, 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 | | |