Mekinist® (trametinib)
(Oral)

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I. Length of Authorization [1,12]

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

- Adjuvant treatment of cutaneous melanoma may be renewed for up to 1 year of therapy.

II. Dosing Limits

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

- Mekinist 0.5 mg tablet: 3 tablets per day
- Mekinist 2 mg tablet: 1 tablet per day
- Mekinist 4.7 mg (0.05 mg/1 mL) oral solution: 40 mL (2 mg) per day

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

- 2 mg daily

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise specified; **AND**
- Patient has not received prior therapy with BRAF and/or MEK inhibitors (e.g., vemurafenib, encorafenib, cobimetinib, binimetinib, etc.) unless otherwise specified; **AND**

Universal Criteria [1]

- 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 does not have colorectal cancer; **AND**

Ampullary Adenocarcinoma ‡ [7]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**

- Used in combination with dabrafenib as subsequent therapy for disease progression

Adult Central Nervous System (CNS) Cancers ‡ [7]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
- Used in combination with dabrafenib; **AND**
    - Used as adjuvant treatment for incomplete resection, biopsy, or surgically inaccessible location; **AND**
        - Patient has pilocytic astrocytoma OR pleomorphic xanthoastrocytoma (grade 2) OR ganglioglioma; **OR**
    - Patient has recurrent or progressive glioblastoma; **OR**
    - Patient has recurrent or progressive circumscribed glioma; **AND**
        - Patient has received prior fractionated external beam radiation therapy; **OR**
    - Used for brain metastases in patients with BRAF V600E mutation-positive melanoma; **AND**
        - Used as initial treatment in patients with small asymptomatic brain metastases; **OR**
        - Patient has recurrent limited brain metastases; **OR**
        - Used for relapsed disease in patients with limited brain metastases and either stable systemic disease or reasonable systemic treatment options; **OR**
        - Used for recurrent disease in patients with extensive brain metastases and stable systemic disease or reasonable systemic treatment options

Esophageal and Esophagogastric Junction Cancer ‡ [7]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
- Patient has adenocarcinoma or squamous cell carcinoma histology; **AND**
- Used in combination with dabrafenib; **AND**
- Used palliatively as subsequent therapy; **AND**
- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease

Gastric Cancer ‡ [7]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
- Patient has adenocarcinoma histology; **AND**
- Used in combination with dabrafenib; **AND**
- Used palliatively as subsequent therapy; **AND**

- Patient is not a surgical candidate or has unresectable locally advanced, recurrent, or metastatic disease

Gastrointestinal Stromal Tumors (GIST) ‡ [7]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
- Used in combination with dabrafenib; **AND**
    - Used as neoadjuvant therapy; **AND**
        - Used for resectable disease with significant morbidity; **OR**
    - Used as first-line therapy; **AND**
        - Used for gross residual (R2 resection), unresectable primary, recurrent, or metastatic disease OR tumor rupture

Head and Neck Cancer ‡ [7]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
- Patient has salivary gland tumors; **AND**
- Used in combination with dabrafenib; **AND**
- Used for one of the following:
    - Distant metastases; **OR**
    - Unresectable locoregional recurrence with prior radiation therapy (RT); **OR**
    - Unresectable second primary with prior RT

Histiocytic Neoplasms ‡ [7]

- Used as single agent therapy; **AND**
- Patient has a mitogen-activated protein (MAP) kinase pathway mutation, or no detectable mutation, or testing not available; **AND**
- Patient has one of the following:
    - Relapsed/refractory or symptomatic Erdheim-Chester Disease (ECD); **OR**
    - Rosai-Dorfman Disease; **AND**
        - Patient has symptomatic unresectable (bulky/site of disease) unifocal disease; **OR**
        - Patient has symptomatic multifocal disease; **OR**
        - Patient has relapsed or refractory disease; **OR**
    - Langerhans Cell Histiocytosis (LCH); **AND**
        - Patient has multisystem disease with symptomatic or impending organ dysfunction or critical organ involvement; **OR**
        - Patient has single-system lung disease; **OR**

- Patient has multifocal single system bone disease not responsive to treatment with a bisphosphonate; **OR**
- Patient has CNS lesions; **OR**
- Patient has relapsed or refractory disease

Cutaneous Melanoma † ‡ Φ [1,7]

- Patient has BRAF V600 mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
  - Used as first-line therapy in combination with dabrafenib OR as a single agent for unresectable or metastatic** disease †; **OR**
  - Used as initial treatment for limited resectable disease; **AND**
    - Used in combination with dabrafenib; **AND**
      - Patient has stage III disease with clinical satellite/in-transit metastases; **OR**
      - Patient has local satellite/in-transit recurrence; **OR**
  - Used as adjuvant therapy in combination with dabrafenib; **AND**
    - Patient has lymph node involvement following complete resection †; **OR**
    - Patient has stage III disease; **AND**
      - Patient has resected sentinel node positive disease either during observation without additional nodal surgery and with mandatory radiographic nodal surveillance OR after complete lymph node dissection (CLND); **OR**
      - Patient has clinically positive node(s) following wide excision of the primary tumor and therapeutic lymph node dissection (TLND) OR following neoadjuvant therapy; **OR**
      - Patient has clinical satellite/in-transit metastases and no evidence of disease (NED) after complete excision to clear margins; **OR**
    - Patient has local satellite/in-transit recurrence and NED after complete excision to clear margins; **OR**
    - Patient has resectable disease limited to nodal recurrence following excision and complete TLND OR following neoadjuvant therapy; **OR**
  - Used subsequent therapy; **AND**
    - Used in combination with dabrafenib; **AND**
      - Used for unresectable or metastatic** disease that has progressed; **OR**
      - Used as re-induction therapy in patients with unresectable or metastatic** disease who experience disease control (i.e., complete response, partial response, or stable disease and no residual toxicity) from prior MEK inhibitor therapy, but subsequently have disease progression/relapse >3 months after treatment discontinuation; **OR**

        - Used in combination with pembrolizumab and dabrafenib; **AND**
            - Used for metastatic or unresectable disease with disease progression or intolerance if BRAF/MEK and/or PD(L)-1 checkpoint inhibition not previously used; **OR**
            - Used as re-induction therapy in patients who experienced disease control (i.e., complete response, partial response, or stable disease with no residual toxicity) from prior combination BRAF/MEK + PD(L)-1 checkpoint inhibitor therapy, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **OR**
- Patient has BRAF gene fusion- and non-V600 mutation-positive disease; **AND**
    - Used as a single agent for unresectable or metastatic disease; **AND**
    - Used as subsequent therapy for disease progression or intolerance

***Metastatic disease includes stage III unresectable/borderline resectable disease with clinically positive node(s) or clinical satellite/in transit metastases, as well as unresectable local satellite/in-transit recurrence, unresectable nodal recurrence, and widely disseminated distant metastatic disease.*

Uveal Melanoma ‡ [7]

- Used as a single agent for treatment of unresectable or metastatic disease

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

- Patient has BRAF V600E mutation-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 with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
- Used in combination with dabrafenib

Ovarian Cancer (including Fallopian Tube and Primary Peritoneal Cancer) ‡ [7]

- Used in combination with dabrafenib; **AND**
    - Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
        - Patient has persistent or recurrent 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; **OR**
- Used as a single agent; **AND**
    - Patient has recurrent low-grade serous carcinoma

Pancreatic Adenocarcinoma ‡ [7]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
- Used in combination with dabrafenib; **AND**
- Patient has good performance status (ECOG PS 0-1 with good biliary drainage and adequate nutritional intake) OR poor PS (ECOG PS 3-4); **AND**
- Used as subsequent therapy for locally advanced, metastatic, progressive, or recurrent disease

Pediatric Central Nervous System (CNS) Cancers † ‡ [1,7,17,26]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
- Used in in combination with dabrafenib; **AND**
    - Patient has low-grade glioma † Φ; **AND**
        - Patient is ≥ 1 year of age and < 18 years of age; **AND**
        - Patient requires systemic therapy; **OR**
    - Patient has diffuse high-grade glioma ‡; **AND**
        - Used as adjuvant therapy *(excluding diffuse midline glioma, H3 K27-altered or pontine location)*; **AND**
            - Patient is < 3 years of age; **OR**
            - Patient is ≥ 3 years of age and ≤ 18 years of age; **AND**
                - Used following standard brain radiation therapy (RT) with or without concurrent temozolomide; **OR**
        - Used for recurrent or progressive disease *(excluding oligodendroglioma, IDH-mutant and 1p/19q co-deleted or astrocytoma IDH-mutant)*; **AND**
            - Patient is ≤ 18 years of age

Anaplastic Thyroid Cancer (ATC) † Φ [1,7]

- Patient has BRAF V600E mutation-positive disease as detected by an FDA approved or CLIA compliant test*; **AND**
- Used in combination with dabrafenib; **AND**
    - Patient has locally advanced disease with no satisfactory locoregional treatment options; **OR**
    - Patient has metastatic disease

Solid Tumors with *BRAF V600E* mutation † ‡ [1,7,14,15]

- Patient is at least 1 year of age; **AND**

- Patient has BRAF V600E mutation-positive solid tumors as detected by an FDA approved or CLIA compliant test*; **AND**
- Patient has unresectable or metastatic disease that has progressed following prior treatment; **AND**
- Patient has no satisfactory alternative treatment options; **AND**
- Used in combination with dabrafenib; **AND**
- Patient has one of the following solid tumors ¥:
    - Thyroid Carcinoma (Anaplastic Carcinoma, Follicular Carcinoma, Oncocytic Carcinoma, Papillary Carcinoma)
    - Biliary Tract Cancers (Gallbladder Cancer, Intra-/Extra-hepatic Cholangiocarcinoma)
    - Adenocarcinoma of the Small Intestine
    - High or Low Grade Glioma
    - Low-Grade Serous Ovarian Carcinoma
    - Neuroendocrine and Adrenal Tumors (Extrapulmonary Poorly Differentiated Neuroendocrine Carcinoma/Large or Small Cell Carcinoma/Mixed Neuroendocrine-Non-Neuroendocrine Neoplasm)
    - Occult Primary

¥ Note: Solid tumors not listed, that are BRAF V600E mutation-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); Φ Orphan Drug

IV. Renewal Criteria [1]

Coverage can be renewed based upon 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: interstitial lung disease/pneumonitis, cardiomyopathy, new primary malignancies, severe hemorrhagic events, colitis/gastrointestinal perforation, venous thromboembolic events (e.g., deep vein thrombosis [DVT], pulmonary embolism [PE], etc.), ocular toxicities (e.g., persistent retinal pigment epithelial detachment [RPED], retinal vein occlusion [RVO], etc.), serious skin toxicities (e.g., Stevens-Johnson syndrome [SJS], drug reaction with eosinophilia and systemic symptoms [DRESS], etc.), serious febrile reactions, hyperglycemia, hemophagocytic lymphohistiocytosis (HLH), etc.; **AND**

- Left ventricular ejection fraction (LVEF) has not had an absolute decrease of ≥ 10% from baseline and is not below the lower limit of normal (LLN) *(LVEF results must be within the previous 3 months)*; **AND**

Adjuvant treatment of Cutaneous Melanoma [1,12]

- Treatment has not exceeded 1 year of therapy

Cutaneous Melanoma (re-induction therapy) [7]

- *Refer to Section III for criteria (see Cutaneous Melanoma – Used as re-induction therapy)*

V. Dosage/Administration [1,9-12,14,15,17-24,28,29]

<table>
<tr><th>Indication</th><th>Dose</th></tr>
<tr><td>Ampullary Adenocarcinoma, Adult CNS Cancers, Esophageal/ Esophagogastric Junction Cancer, Gastric Cancer, GIST, Head and Neck Cancer, Histiocytic Neoplasms, Cutaneous Melanoma, Uveal Melanoma, NSCLC, Ovarian Cancer, Pancreatic Cancer, ATC</td><td>Administer 2 mg orally once daily until disease progression/recurrence or unacceptable toxicity
(Note: for adjuvant treatment of cutaneous melanoma, treat until disease recurrence or unacceptable toxicity for up to 1 year).</td></tr>
<tr><td>Solid Tumors with BRAF V600E mutation</td><td><u>Adult Patients</u>
Administer 2 mg orally once daily until disease progression/recurrence or unacceptable toxicity

<u>Pediatric Patients</u>
– Tablets (for use in patients weighing at least 26 kg):
<table>
<tr><th>Body weight</th><th>Recommended dosage</th></tr>
<tr><td>26 to 37 kg</td><td>1 mg orally once daily</td></tr>
<tr><td>38 to 50 kg</td><td>1.5 mg orally once daily</td></tr>
<tr><td>51 kg or greater</td><td>2 mg orally once daily</td></tr>
</table>
– Oral Solution:
<table>
<tr><th>Body weight</th><th>Recommended dosage total volume of oral solution once daily (trametinib content)</th></tr>
<tr><td>8 kg</td><td>6 mL (0.3 mg)</td></tr>
<tr><td>9 kg</td><td>7 mL (0.35 mg)</td></tr>
<tr><td>10 kg</td><td>7 mL (0.35 mg)</td></tr>
<tr><td>11 kg</td><td>8 mL (0.4 mg)</td></tr>
<tr><td>12 to 13 kg</td><td>9 mL (0.45 mg)</td></tr>
<tr><td>14 to 17 kg</td><td>11 mL (0.55 mg)</td></tr>
<tr><td>18 to 21 kg</td><td>14 mL (0.7 mg)</td></tr>
<tr><td>22 to 25 kg</td><td>17 mL (0.85 mg)</td></tr>
<tr><td>26 to 29 kg</td><td>18 mL (0.9 mg)</td></tr>
<tr><td>30 to 33 kg</td><td>20 mL (1 mg)</td></tr>
<tr><td>34 to 37 kg</td><td>23 mL (1.15 mg)</td></tr>
</table>
</td></tr>
</table>

<table>
<tr><td></td><td>
<table>
<tr><td>38 to 41 kg</td><td>25 mL (1.25 mg)</td></tr>
<tr><td>42 to 45 kg</td><td>28 mL (1.4 mg)</td></tr>
<tr><td>46 to 50kg</td><td>32 mL (1.6 mg)</td></tr>
<tr><td>≥ 51 kg</td><td>40 mL (2 mg)</td></tr>
</table>
***Administer until disease progression or unacceptable toxicity</td></tr>
<tr><td>Pediatric CNS Cancers</td><td><u>Low-Grade Glioma</u>
– Tablets (for use in patients weighing at least 26 kg):
<table>
<tr><th>Body weight</th><th>Recommended dosage</th></tr>
<tr><td>26 to 37 kg</td><td>1 mg orally once daily</td></tr>
<tr><td>38 to 50 kg</td><td>1.5 mg orally once daily</td></tr>
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<tr><td>18 to 21 kg</td><td>14 mL (0.7 mg)</td></tr>
<tr><td>22 to 25 kg</td><td>17 mL (0.85 mg)</td></tr>
<tr><td>26 to 29 kg</td><td>18 mL (0.9 mg)</td></tr>
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<tr><td>42 to 45 kg</td><td>28 mL (1.4 mg)</td></tr>
<tr><td>46 to 50kg</td><td>32 mL (1.6 mg)</td></tr>
<tr><td>≥ 51 kg</td><td>40 mL (2 mg)</td></tr>
</table>
***Administer until disease progression or unacceptable toxicity.

<u>High-Grade Glioma</u>
Administer up to 2 mg orally once daily until disease progression/recurrence or unacceptable toxicity.</td></tr>
</table>

VI. Billing Code/Availability Information

<u>HCPCS Code:</u>

- J8999 – Prescription drug oral, chemotherapeutic, Not Otherwise Specified

<u>NDC(s):</u>

- Mekinist 0.5 mg tablet: 00078-0666-xx
- Mekinist 0.5 mg tablet: 00078-1105-xx
- Mekinist 2 mg tablet: 00078-0668-xx
- Mekinist 2 mg tablet: 00078-1112-xx
- Mekinist 4.7 mg (0.05 mg/1 mL) oral solution: 00078-1161-xx

VII. References

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28. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Esophageal and Esophagogastric Junction Cancers. Version 3.2023. National Comprehensive Cancer Network, 2023. 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 September 2023.
29. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) Gastric Cancer. Version 2.2023. National Comprehensive Cancer Network, 2023. 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 September 2023.
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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

ICD-10	ICD-10 Description
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 of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
C17.8	Malignant neoplasm of overlapping sites of small intestine
C17.9	Malignant neoplasm of small intestine, unspecified
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 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

ICD-10	ICD-10 Description
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
C43.0	Malignant melanoma of lip
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of left lower eyelid, including canthus
C43.121	Malignant melanoma of left upper eyelid, including canthus
C43.122	Malignant melanoma of left lower eyelid, including canthus
C43.20	Malignant melanoma of unspecified ear and external auricular canal
C43.21	Malignant melanoma of right ear and external auricular canal
C43.22	Malignant melanoma of left ear and external auricular canal
C43.30	Malignant melanoma of unspecified part of face
C43.31	Malignant melanoma of nose
C43.39	Malignant melanoma of other parts of face
C43.4	Malignant melanoma of scalp and neck
C43.51	Malignant melanoma of anal skin
C43.52	Malignant melanoma of skin of breast
C43.59	Malignant melanoma of other part of trunk
C43.60	Malignant melanoma of unspecified upper limb, including shoulder
C43.61	Malignant melanoma of right upper limb, including shoulder
C43.62	Malignant melanoma of left upper limb, including shoulder
C43.70	Malignant melanoma of unspecified lower limb, including hip
C43.71	Malignant melanoma of right lower limb, including hip
C43.72	Malignant melanoma of left lower limb, including hip

ICD-10	ICD-10 Description
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
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.A0	Gastrointestinal stromal tumor, unspecified site
C49.A1	Gastrointestinal stromal tumor of esophagus
C49.A2	Gastrointestinal stromal tumor of stomach
C49.A3	Gastrointestinal stromal tumor of small intestine
C49.A4	Gastrointestinal stromal tumor of large intestine
C49.A5	Gastrointestinal stromal tumor of rectum
C49.A9	Gastrointestinal stromal tumor of other sites
C49.4	Malignant neoplasm of connective and soft tissue of abdomen
C49.5	Malignant neoplasm of connective and soft tissue of pelvis
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue
C49.9	Malignant neoplasm of connective and soft tissue, 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
C69.30	Malignant neoplasm of unspecified choroid

ICD-10	ICD-10 Description
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body
C69.41	Malignant neoplasm of right ciliary body
C69.42	Malignant neoplasm of left ciliary body
C69.60	Malignant neoplasm of unspecified orbit
C69.61	Malignant neoplasm of right orbit
C69.62	Malignant neoplasm of left orbit
C7A.1	Malignant poorly differentiated neuroendocrine tumors
C7A.8	Other malignant neuroendocrine tumors
C7B.8	Other secondary neuroendocrine tumors
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles
C71.1	Malignant neoplasm of frontal lobe
C71.2	Malignant neoplasm of temporal lobe
C71.3	Malignant neoplasm of parietal lobe
C71.4	Malignant neoplasm of occipital lobe
C71.5	Malignant neoplasm of cerebral ventricle
C71.6	Malignant neoplasm of cerebellum
C71.7	Malignant neoplasm of brain stem
C71.8	Malignant neoplasm of overlapping sites of brain
C71.9	Malignant neoplasm of brain, unspecified
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
C72.9	Malignant neoplasm of central nervous system, unspecified
C73	Malignant neoplasm of thyroid gland
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

ICD-10	ICD-10 Description
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
D43.0	Neoplasm of uncertain behavior of brain, supratentorial
D43.1	Neoplasm of uncertain behavior of brain, infratentorial
D43.2	Neoplasm of uncertain behavior of brain, unspecified
D43.4	Neoplasm of uncertain behavior of spinal cord
D43.9	Neoplasm of uncertain behavior of central nervous system, 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
Z85.068	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
Z85.43	Personal history of malignant neoplasm of ovary
Z85.820	Personal history of malignant melanoma of skin
Z85.831	Personal history of malignant neoplasm of soft tissue
Z85.841	Personal history of malignant neoplasm of brain
Z85.848	Personal history of malignant neoplasm of other parts of nervous 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 Articles (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)

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, 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