Yervoy® (ipilimumab)
(Intravenous)

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I. Length of Authorization Δ 1,5,6,8-12,17-19,20,24,27-29,31,33,39-42,44

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

- The following indications may be authorized up to a maximum of twelve (12) weeks of therapy and may NOT be renewed *(coverage may be extended to 16 weeks if 4 doses were not administered within the 12 week time frame)*:
  - Colorectal Cancer *(subsequent therapy/disease progression)*
  - CNS metastases from Melanoma *(combination therapy with nivolumab)*
  - Cutaneous Melanoma *(first-line or subsequent therapy)*
    ***** *Requests for Cutaneous Melanoma may be renewed if the patient meets the provisions for re-induction therapy.*
  - Hepatocellular Carcinoma
  - Renal Cell Carcinoma
  - Uveal Melanoma
- The following indications may be renewed up to a maximum of two (2) years of therapy:
  - Non-Small Cell Lung Cancer
  - Esophageal Cancer
  - Malignant Pleural Mesothelioma

Cutaneous Melanoma (adjuvant treatment – maintenance therapy)

- Coverage for adjuvant treatment will be provided for six (6) months and may be renewed for up to a maximum of three (3) years of maintenance therapy.

II. Dosing Limits

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

- Yervoy 200 mg/40 mL injection:
  - 5 vials per 84 days (initially up to 5 vials per 21 days x 4 doses)
- Yervoy 50 mg/10 mL injection:
  - 3 vials per 84 days (initially up to 3 vials per 21 days x 4 doses)

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

Indication	Billable Units (BU)	Per unit time (days)
HCC	350 BU	21 days x 4 doses
Cutaneous Melanoma, CNS metastases	Initial: 1150 BU	Initial: 21 days x 4 doses
	Followed by: 1150 BU	Followed by: 84 days
Uveal Melanoma	1150 BU	21 days x 4 doses
RCC	150 BU	21 days x 4 doses
CRC, Esophageal Cancer, MPM, NSCLC	150 BU	42 days

III. Initial Approval Criteria [1]

Coverage is provided in the following conditions:

- Patient is at least 18 years of age, unless otherwise indicated; **AND**

Central Nervous System (CNS) Cancer ‡ [2,4,8,10,11,27,82e]

- Used for the treatment of brain metastases in patients with BRAF non-specific melanoma; **AND**
- Used in combination with nivolumab or as a single agent; **AND**
- Used in one of the following treatment settings:
  - Used as initial treatment in patients with small asymptomatic brain metastases
  - Used for relapsed limited brain metastases with either stable systemic disease or reasonable systemic treatment options
  - Patient has recurrent limited brain metastases
  - Used for recurrent extensive brain metastases with stable systemic disease or reasonable systemic treatment options; **AND**

Ipilimumab as a single-agent ONLY:

- Use of ipilimumab as a single agent will be restricted to patients with a contraindication or intolerance to nivolumab

Colorectal Cancer (CRC) † [1,2,19,31,42,85e-87e]

- Patient is at least 12 years of age; **AND**
- Patient's disease must be microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Patient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.) Δ; **AND**
- Used in combination with nivolumab*; **AND**
  - Used as subsequent therapy for advanced or metastatic disease that progressed following treatment with a fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy † ‡; **AND**
    - Patient must use single-agent pembrolizumab or nivolumab; **OR**

- Used as primary treatment; **AND**
  - Used for unresectable (or medically inoperable) or metastatic disease; **AND**

▪ Use of ipilimumab will be restricted to patients with a contraindication or intolerance to pembrolizumab

** Single agent nivolumab should be used in patients who are not candidates for intensive therapy.*

Esophageal Cancer † [1,2,45,105e]

- Patient has esophageal squamous cell carcinoma (ESCC); **AND**
- Used as first-line treatment of unresectable advanced or metastatic disease; **AND**
- Used in combination with nivolumab; **AND**

• Use of ipilimumab in combination with nivolumab will be restricted to patients with a contraindication or intolerance to one of the following: – Nivolumab in combination with fluorouracil and cisplatin – Pembrolizumab in combination with fluoropyrimidine- and platinum-containing chemotherapy (if PD-L1 CPS ≥10)

Hepatocellular Carcinoma (HCC) † [1,2,30,30e,31e,33e,34e]

- Used in combination with nivolumab; **AND**
- Used as subsequent therapy for progressive disease; **AND**
- Patient progressed on or was intolerant to sorafenib or lenvatinib; **AND**
- Patient has Child-Pugh Class A hepatic impairment; **AND**
- Used for one of the following:
  - Patient has unresectable disease and is not a transplant candidate
  - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic-disease
  - Patient has metastatic disease or extensive liver tumor burden; **AND**

• Use of ipilimumab in combination with nivolumab will be restricted to patients with a contraindication or intolerance to regorafenib or cabozantinib; **AND** <u>Patients with AFP ≥ 400 ng/mL ONLY:</u> • Use of ipilimumab will be restricted to patients with a contraindication or intolerance to ramucirumab

Renal Cell Carcinoma (RCC) † ‡ [1,2,18]

- Used in combination with nivolumab for clear cell histology; **AND**
  - Used as first-line therapy patients with advanced, relapsed, or stage IV disease with poor or intermediate risk; **OR**
  - Used as first-line therapy patients with relapsed or stage IV disease with favorable risk

Malignant Pleural Mesothelioma (MPM) † ‡ Φ [1,2,5,25,26,34,37]

- Used in combination with nivolumab; **AND**
    - Used as subsequent therapy (if not administered first-line); **OR**
    - Used as first-line therapy in patients with medically inoperable tumors or unresectable disease

**Note: Pericardial and tunica vaginalis testis mesothelioma will be evaluated on a case-by-case basis.*

Cutaneous Melanoma † ‡ Φ [1,2,6,17,43,5e,8e,11e,13e,21e-23e,99e,100e]

- Used as first-line therapy for unresectable or metastatic disease in combination with nivolumab †; **OR**
- Used as subsequent therapy for unresectable or metastatic* disease; **AND**
    - Used after disease progression or after maximum clinical benefit from BRAF-targeted therapy (e.g., dabrafenib/trametinib, vemurafenib/cobimetinib, encorafenib/binimetinib, etc.); **AND**
        - Used as a single agent in patients at least 12 years of age if not previously used alone or in combination with anti-PD-1 immunotherapy †; **AND**
            - Patient was previously treated with cytotoxic chemotherapy or interleukin-2; **AND**

            Patients ≥ 18 years of age:

            - Use of ipilimumab will be restricted to patients with a contraindication or intolerance to nivolumab or pembrolizumab; **OR**
        - Used in combination with nivolumab if not previously used or for patients who progress on single agent anti-PD-1 therapy; **OR**
        - Used in combination with pembrolizumab if not previously used alone or in combination with anti-PD-1 therapy for patients who progress on single agent anti-PD-1 therapy; **OR**
    - Used as re-induction therapy in patients who experienced disease control *(i.e., complete or partial response or stable disease)* and no residual toxicity from prior use, but subsequently have disease progression/relapse > 3 months after treatment discontinuation; **AND**
        - Used as a single agent; **AND**
        - Patient has completed initial induction ipilimumab therapy (i.e., completion of 4 cycles within a 16 week period); **OR**
- Used as a single agent for adjuvant therapy; **AND**
    - Patient has stage III disease with pathologic involvement of regional lymph nodes of more than 1 mm and has undergone complete resection including total lymphadenectomy †; **AND**

- Use of ipilimumab for adjuvant therapy will be restricted to patients with a contraindication or intolerance to pembrolizumab or nivolumab

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

Uveal Melanoma ‡ [2,20-23,32]

- Patient has distant metastatic disease; **AND**
  - Used as a single agent; **OR**
  - Used in combination with ipilimumab as first-line therapy

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,12,16,24,36,35e-37e,43e,50e,89e]

- Used for 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; **AND**
  - Used as first-line therapy; **AND**
    - Used for one of the following:
      - Patients with a performance status (PS) 0-1 who have tumors that are negative for actionable molecular biomarkers****** and PD-L1 <1%
      - Used in patients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement
      - PD-L1 expression positive (PD-L1 ≥1%) tumors, as detected by an FDA or CLIA compliant test❖, that are tumors that are negative for actionable molecular biomarkers******; **AND**
    - Used in combination with one of the following:
      - Nivolumab
      - Nivolumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for nonsquamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); **AND**

<u>PD-L1 expression ≥50%:</u>

- Use of ipilimumab in combination with nivolumab (with or without platinum-doublet chemotherapy) will be restricted to patients with a contraindication or intolerance to cemiplimab; **OR**

<u>PD-L1 <50% or EGFR exon 20, KRAS G12C, BRAF V600E, NTRK1/2/3 gene fusion, MET exon-14 skipping, or RET rearrangement positive tumors:</u>

Squamous NSCLC:

- Use of ipilimumab in combination with nivolumab (with or without platinum-doublet chemotherapy) will be restricted to patients with a contraindication or intolerance to pembrolizumab/carboplatin/(paclitaxel or albumin-bound paclitaxel***); **OR**

  ****Albumin-bound paclitaxel may be used in place of paclitaxel in patients who meet the taxane-hypersensitivity criteria in Abraxane-E.*

Nonsquamous NSCLC:

- Use of ipilimumab in combination with nivolumab (with or without platinum-doublet chemotherapy) will be restricted to patients with a contraindication or intolerance to pembrolizumab/(carboplatin or cisplatin)/pemetrexed; **OR**

- Used as subsequent therapy; **AND**
  - Used for one of the following:
    - Patients with a PS 0-1 who received prior targeted therapy§ for one of the following molecular biomarkers: EGFR S768I, L861Q, and/or G719X, or ROS1 rearrangement
    - Patients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **AND**
  - Used in combination with one of the following:
    - Nivolumab
    - Nivolumab, pemetrexed, and either carboplatin or cisplatin for nonsquamous cell histology
    - Nivolumab, paclitaxel, and carboplatin for squamous cell histology; **AND**

Squamous NSCLC:

- Use of ipilimumab in combination with nivolumab (with or without platinum-doublet chemotherapy) will be restricted to patients with a contraindication or intolerance to pembrolizumab/carboplatin/(paclitaxel or albumin-bound paclitaxel***); **OR**

  ****Albumin-bound paclitaxel may be used in place of paclitaxel in patients who meet the taxane-hypersensitivity criteria in Abraxane-E.*

Nonsquamous NSCLC:

- Use of ipilimumab in combination with nivolumab (with or without platinum-doublet chemotherapy) will be restricted to patients with a contraindication or intolerance to pembrolizumab/(carboplatin or cisplatin)/pemetrexed; **OR**

- Used as continuation maintenance therapy in combination with nivolumab; **AND**
  - Patient has achieved a response or stable disease following first-line therapy with nivolumab and ipilimumab with or without chemotherapy

*** Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET exon 14 skipping mutation, and RET rearrangement. If there is insufficient tissue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, and RET, repeat biopsy and/or plasma testing should be done. If these are not feasible, treatment is guided by available results and, if unknown, these patients are treated as though they do not have driver oncogenes.*

Preferred therapies and recommendations are determined by review of clinical evidence. NCCN category of recommendation is taken into account as a component of this review. Regimens deemed equally efficacious (i.e., those having the same NCCN categorization) are considered to be therapeutically equivalent.

❖ *If confirmed using an immunotherapy assay-http://www.fda.gov/CcompanionDiagnostics*

† FDA approved indication(s); ‡ Compendia recommended indication; Φ Orphan Drug

Genomic Aberration/Mutational Driver Targeted Therapies (Note: *not all inclusive, refer to guidelines for appropriate use*) §				
Sensitizing *EGFR* mutation-positive tumors	*ALK* rearrangement-positive tumors	*ROS1* rearrangement-positive tumors	*BRAF* V600E-mutation positive tumors	*NTRK1/2/3* gene fusion positive tumors
– Afatinib – Erlotinib – Dacomitinib – Gefitinib – Osimertinib – Amivantamab *(exon-20 insertion)* – Mobocertinib *(exon-20 insertion)*	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib	– Dabrafenib ± trametinib – Vemurafenib	– Larotrectinib – Entrectinib
PD-L1 tumor expression ≥1%	PD-L1 tumor expression ≥50%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors
– Pembrolizumab – Atezolizumab – Nivolumab ± ipilimumab	– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib

IV. Renewal Criteria Δ 1,2,6,9-12,17-29,39-41

Coverage may be renewed based upon the following criteria:

- Patient continues to meet the universal and other indication-specific relevant criteria such as concomitant therapy requirements (not including prerequisite therapy), performance status, etc. identified in section III; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: immune-mediated reactions (e.g., colitis, hepatitis, dermatitis/skin adverse reactions, pneumonitis, nephritis/renal dysfunction, endocrinopathies, etc.), severe infusion reactions, complications of allogeneic hematopoietic stem cell transplantation (HSCT), etc.; **AND**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**

- Coverage may NOT be renewed for the following indications:
  - Renal Cell Carcinoma
  - Colorectal Cancer *(subsequent therapy/disease progression)*
  - Hepatocellular Carcinoma
  - Cutaneous Melanoma *(first-line or subsequent therapy)*
  - Uveal Melanoma
  - CNS metastases from Melanoma *(combination therapy with nivolumab)*
- For the following indications, patient has not exceeded a maximum of two (2) years of therapy:
  - Non-Small Cell Lung Cancer
  - Esophageal Cancer
  - Malignant Pleural Mesothelioma

Cutaneous Melanoma (re-induction therapy) ‡

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

Cutaneous Melanoma (adjuvant treatment – maintenance therapy)

- Patient has not exceeded a maximum of three (3) years of therapy

Non-Small Cell Lung Cancer (continuation maintenance therapy)

- *Refer to Section III for criteria*

Δ Notes:

- Patients responding to therapy who relapse ≥ 6 months after discontinuation due to duration (i.e., receipt of 24 months of PD-directed therapy) are eligible to re-initiate checkpoint inhibitor therapy.
- Patients who complete adjuvant therapy and progress ≥ 6 months after discontinuation are eligible to re-initiate checkpoint inhibitor therapy for metastatic disease.
- Patients whose tumors, upon re-biopsy, demonstrate a change in actionable mutation (e.g., MSS initial biopsy; MSI-H subsequent biopsy) may be eligible to re-initiate checkpoint inhibitor therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ [1,5,6,8-12,17-29,31,33,34,38,39-42,44]

Indication	Dose
Renal Cell Carcinoma (RCC)	Administer 1 mg/kg intravenously every 3 weeks for a total of 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)
CNS metastases from Melanoma	Single agent: ○ Initial: Administer 10 mg/kg intravenously every 3 weeks for 4 doses

	○ Subsequent (starting at week 24): Administer 10 mg/kg intravenously every 12 weeks until disease progression or unacceptable toxicity In combination with nivolumab: ○ Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)
Colorectal Cancer (CRC)	Primary/initial treatment ○ Administer 1 mg/kg intravenously every 6 weeks, with nivolumab every 2 weeks, until disease progression or unacceptable toxicity Subsequent therapy/disease progression ○ Administer 1 mg/kg intravenously every 3 weeks for a total of 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)
Esophageal Cancer	Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab) until disease progression or unacceptable toxicity for up to 2 years
Hepatocellular Carcinoma (HCC)	Administer 3 mg/kg intravenously every 3 weeks for a total of 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)
Malignant Pleural Mesothelioma (MPM)	Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab) until disease progression or unacceptable toxicity for up to 2 years
Cutaneous Melanoma *(excluding adjuvant therapy)*	Single agent or in combination with nivolumab: ○ Administer 3 mg/kg intravenously every 3 weeks for a maximum of 4 doses (when given in combination with nivolumab, follow with nivolumab monotherapy) In combination with pembrolizumab as subsequent therapy: ○ Administer 1 mg/kg intravenously every 3 weeks for a maximum of 4 doses (given in combination with pembrolizumab, then follow with pembrolizumab monotherapy)
Cutaneous Melanoma (adjuvant therapy)	○ Initial: Administer 10 mg/kg intravenously every 3 weeks for 4 doses ○ Maintenance: Administer 10 mg/kg intravenously every 12 weeks for up to 3 years
Uveal Melanoma	Single agent: ○ Administer 3 mg/kg or 10mg/kg intravenously every 3 weeks for 4 doses In combination with nivolumab: ○ Administer 3 mg/kg intravenously 3 weeks for 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)
Non-Small Cell Lung Cancer (NSCLC)	In combination with nivolumab: ○ Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab every 2 weeks), until disease progression or unacceptable toxicity for up to 2 years In combination with nivolumab and platinum-doublet chemotherapy: ○ Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab every 3 weeks and 2 cycles of histology-based platinum-doublet chemotherapy every 3 weeks), until disease progression or unacceptable toxicity for up to 2 years
** All treatments given for a maximum of 4 doses must be administered within 16 weeks of the first dose.*	

VI. Billing Code/Availability Information

HCPCS Code:

- J9228 – Injection, ipilimumab, 1 mg: 1 billable unit = 1 mg

NDC(s):

- Yervoy 200 mg/40 mL injection (single-dose vial): 00003-2328-xx
- Yervoy 50 mg/10 mL injection (single-dose vial): 00003-2327-xx

VII. References (STANDARD)

1. Yervoy [package insert]. Princeton, NJ; Bristol Meyers Squib; May 2022. Accessed June 2022.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ipilimumab. National Comprehensive Cancer Network, 2022. 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 June 2022.
3. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Small Cell Lung Cancer. Version 2.2022. National Comprehensive Cancer Network, 2022. 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 Guidelines, go online to NCCN.org. Accessed June 2022.
4. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Central Nervous System Cancers. Version 2.2021. National Comprehensive Cancer Network, 2022. 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 Guidelines, go online to NCCN.org. Accessed June 2022.
5. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Malignant Pleural Mesothelioma. Version 1.2022. National Comprehensive Cancer Network, 2022. 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 Guidelines, go online to NCCN.org. Accessed June 2022.
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Appendix 1 – Covered Diagnosis Codes

ICD-10	ICD-10 Description
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

ICD-10	ICD-10 Description
C16.0	Malignant neoplasm of cardia
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.8	Malignant neoplasm of overlapping sites of small intestine
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 colon
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
C22.0	Liver cell carcinoma
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
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 and 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

ICD-10	ICD-10 Description
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C43.0	Malignant melanoma of lip
C43.10	Malignant melanoma of unspecified eyelid, including canthus
C43.11	Malignant melanoma of right eyelid, including canthus
C43.12	Malignant melanoma of left eyelid, including canthus
C43.111	Malignant melanoma of right upper eyelid, including canthus
C43.112	Malignant melanoma of right 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
C43.8	Malignant melanoma of overlapping sites of skin
C43.9	Malignant melanoma of skin, unspecified
C45.0	Mesothelioma of pleura
C64.1	Malignant neoplasm of right kidney, except renal pelvis
C64.2	Malignant neoplasm of left kidney, except renal pelvis
C64.9	Malignant neoplasm of unspecified kidney, except renal pelvis
C65.1	Malignant neoplasm of right renal pelvis
C65.2	Malignant neoplasm of left renal pelvis
C65.9	Malignant neoplasm of unspecified renal pelvis
C69.30	Malignant neoplasm of unspecified choroid
C69.31	Malignant neoplasm of right choroid
C69.32	Malignant neoplasm of left choroid
C69.40	Malignant neoplasm of unspecified ciliary body

ICD-10	ICD-10 Description
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
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
D37.8	Neoplasm of uncertain behavior of other specified digestive organs
D37.9	Neoplasm of uncertain behavior of digestive organ, unspecified
Z85.00	Personal history of malignant neoplasm of unspecified digestive organ
Z85.01	Personal history of malignant neoplasm of esophagus
Z85.038	Personal history of other malignant neoplasm of large intestine
Z85.068	Personal history of other malignant neoplasm of small intestine
Z85.118	Personal history of other malignant neoplasm of bronchus and lung
Z85.820	Personal history of malignant melanoma of skin

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)
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.

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