Yervoy® (ipilimumab)
(Intravenous)

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I. Length of Authorization Δ 1,5,6,8-12,17-19,20,24,27-29,31,33,39-42,44,46,49

Coverage will be provided for 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)*
  - Appendiceal Adenocarcinoma *(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.*
  - Cutaneous Melanoma *(adjuvant therapy in combination with nivolumab)*
  - Hepatocellular Carcinoma
  - Renal Cell Carcinoma
  - Small Bowel Adenocarcinoma
  - Ampullary Adenocarcinoma
  - Uveal Melanoma
- The following indications may be renewed up to a maximum of two (2) years of therapy:
  - Bone Cancer
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer
  - Kaposi Sarcoma
  - Malignant Peritoneal Mesothelioma
  - Malignant Pleural Mesothelioma
  - Non-Small Cell Lung Cancer

Cutaneous Melanoma (single agent adjuvant treatment)

- Coverage will be provided for 6 months and may be renewed for up to a maximum of 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, SBA, Ampullary Adenocarcinoma	150 BU	21 days x 4 doses
Bone Cancer, CRC, Appendiceal Adenocarcinoma, Esophageal and Esophagogastric/Gastroesophageal Junction Cancer, MPM, MPeM, NSCLC, Kaposi Sarcoma	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**

Ampullary Adenocarcinoma ‡ [2]

- Patient's disease is microsatellite instability-high (MSI-H) or mismatch repair deficient (dMMR); **AND**
- Used in combination with nivolumab; **AND**
  - Used as first-line therapy for unresectable or metastatic intestinal type disease; **OR**
  - Used as subsequent therapy for disease progression

Bone Cancer ‡ [2,46]

- Patient has one of the following: Ewing sarcoma, Chondrosarcoma *(excluding mesenchymal chondrosarcoma)*, Osteosarcoma, or Chordoma; **AND**
- Patient has tumor mutation burden-high (TMB-H) tumors [≥ 10 mutations/megabase (mut/Mb)] as determined by an FDA-approved or CLIA-compliant test❖; **AND**
- Used in combination with nivolumab; **AND**
- Patient has unresectable or metastatic disease that progressed following prior treatment; **AND**

- Patient has no satisfactory alternative treatment options

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

- 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 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

Colorectal Cancer (CRC) † ‡ [1,2,19,31,42]

- Patient is at least 12 years of age; **AND**
- Patient's disease is 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 one of the following:
        - Fluoropyrimidine-, oxaliplatin-, and/or irinotecan-based chemotherapy † ‡; **OR**
        - Non-intensive therapy in patients with improvement in functional status******; **OR**
    - Used as primary treatment; **AND**
        - Used as neoadjuvant therapy for clinical T4b colon cancer; **OR**
        - Used as neoadjuvant therapy of resectable liver and/or lung metastases; **OR**
        - Used if resection is contraindicated following neoadjuvant therapy for advanced, locally unresectable, or medically inoperable rectal cancer; **OR**
        - Used for unresectable (or medically inoperable) or metastatic disease

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

******** *Except if received previous fluoropyrimidine.*

Appendiceal Adenocarcinoma – Colon Cancer ‡ [2,31]

- Patient's disease is 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 previous oxaliplatin- irinotecan- and/or fluoropyrimidine-based therapy; **OR**
    - Used as initial therapy for advanced or metastatic disease

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

Esophageal Cancer and Esophagogastric/Gastroesophageal Junction Cancers † [1,2,45]

- Patient has esophageal squamous cell carcinoma (ESCC); **AND**
- Patient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.) [Δ]; **AND**
- Used as first-line treatment in combination with nivolumab; **AND**
- Patient is not a surgical candidate or has unresectable advanced, recurrent, or metastatic disease

Hepatocellular Carcinoma (HCC) † ‡ [1,2,30]

- Used in combination with nivolumab; **AND**
- Used as subsequent therapy for progressive disease; **AND**
- Patient has Child-Pugh Class A hepatic impairment; **AND**
    - Patient was previously treated with sorafenib †; **OR**
    - 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

Kaposi Sarcoma ‡ [2,47]

- Used in combination with nivolumab as subsequent therapy; **AND**
- Patient has classic disease; **AND**
- Used for relapsed/refractory advanced cutaneous, oral, visceral, or nodal disease; **AND**
- Disease has progressed on or not responded to first-line therapy; **AND**
- Disease has progressed on alternate first-line therapy

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

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

- Used as first-line therapy in patients with favorable risk relapsed or stage IV disease; **OR**
- Used as subsequent therapy in patients with relapsed or stage IV disease [Δ]

Malignant Peritoneal Mesothelioma* (MPeM) ‡ [2]

- Used in combination with nivolumab; **AND**
  - Used as subsequent therapy (if not administered first-line); **OR**
  - Used as first-line therapy; **AND**
    - Patient has unresectable diffuse disease; **OR**
    - Patient has unresectable recurrent benign multicystic or well-differentiated papillary disease

**Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.*

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; **AND**
    - Patient has stage IIIB or IV disease; **OR**
    - Patient has sarcomatoid or biphasic histology; **OR**
    - Disease is medically inoperable or unresectable; **OR**
    - Patient has unresectable stage I-IIIA disease with epithelioid histology

***Note: May also be used for pericardial mesothelioma and tunica vaginalis testis mesothelioma.*

Cutaneous Melanoma † ‡ Φ [1,2,6,17,43]

- Used as first-line therapy for unresectable or metastatic* disease †; **AND**
  - Patient is at least 12 years of age; **AND**
  - Used as a single agent or in combination with nivolumab; **OR**
- Used as initial therapy for limited resectable local satellite/in-transit recurrence; **AND**
  - Used as a single-agent; **AND**
  - Patient has prior exposure to anti-PD-1 therapy (e.g., nivolumab or pembrolizumab); **OR**
- Used as subsequent therapy for unresectable or metastatic* disease; **AND**
  - Used after disease progression, intolerance, and/or projected risk of progression with 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 therapy †; **OR**

        - Used in combination with nivolumab in patients at least 12 years of age 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 or in combination with anti-PD-1 therapy; **AND**
        - Patient has completed initial induction ipilimumab therapy (i.e., completion of 4 cycles within a 16 week period); **OR**
- Used as adjuvant treatment; **AND**
    - Used as a single agent; **AND**
        - Patient has pathologic involvement of regional lymph nodes of more than 1 mm and has undergone complete resection including total lymphadenectomy †; **OR**
        - Patient has prior exposure to anti-PD-1 therapy (e.g., nivolumab or pembrolizumab); **AND**
            - Patient has local satellite/in-transit recurrence and has no evidence of disease after complete excision ‡; **OR**
            - Patient has resectable disease limited to nodal recurrence following excision and complete therapeutic lymph node dissection (TLND) OR following neoadjuvant therapy ‡; **OR**
            - Patient has oligometastatic disease and no evidence of disease following metastasis-directed therapy (i.e., complete resection, stereotactic ablative therapy or T-VEC/intralesional therapy) or systemic therapy followed by resection ‡; **OR**
    - Used in combination with nivolumab; **AND**
        - Patient has oligometastatic disease and no evidence of disease following metastasis-directed therapy (i.e., complete resection, stereotactic ablative therapy or T-VEC/intralesional therapy) or systemic therapy followed by resection

**Metastatic disease includes stage III unresectable/borderline resectable disease with clinically positive node(s) 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]

- Used as a single agent or in combination with nivolumab; **AND**

- Patient has distant metastatic disease

Non-Small Cell Lung Cancer (NSCLC) † ‡ [1,2,16,24]

- 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%
            - Patients with a PS 0-1 who are positive for one of the following molecular biomarkers: EGFR exon 20, KRAS G12C, BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, RET rearrangement, or ERBB2 (HER2)
            - PD-L1 expression positive (PD-L1 ≥1%) tumors, as detected by an FDA or CLIA compliant test❖, that are negative for actionable molecular biomarkers**; **AND**
                - Used in combination with nivolumab; **OR**
                - Used in combination with nivolumab and platinum-doublet chemotherapy (e.g., pemetrexed and either carboplatin or cisplatin for non-squamous cell histology, or paclitaxel and carboplatin for squamous cell histology, etc.); **OR**
    - Used as subsequent therapy; **AND**
        - Used for one of the following:
            - Patients with a PS 0-1 who are positive for one of the following molecular mutations and have received prior targeted therapy§: EGFR exon 19 deletion or exon 21 L858R tumors, EGFR S768I, L861Q, and/or G719X, ALK rearrangement, or ROS1 rearrangement
            - Patients with a PS 0-1 who are positive for one of the following molecular biomarkers: BRAF V600E, NTRK 1/2/3 gene fusion, MET exon 14 skipping, or RET rearrangement; **AND**
                - Used in combination with nivolumab; **OR**
                - Used in combination with nivolumab, pemetrexed, and either carboplatin or cisplatin for non-squamous cell histology; **OR**
                - Used in combination with nivolumab, paclitaxel and carboplatin for squamous cell histology; **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, RET rearrangement, and ERBB2 (HER2). If there is insufficient tissue to allow testing for all of EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, RET, and ERBB2 (HER2), 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.*

Small Bowel Adenocarcinoma (SBA) ‡ [2,19,29]

- Patient has advanced or metastatic disease that is 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 initial therapy; **OR**
  - Used as subsequent therapy for patients with no prior oxaliplatin exposure in the adjuvant treatment setting and no contraindication to oxaliplatin therapy

❖ *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%	*MET* exon-14 skipping mutations	*RET* rearrangement-positive tumors	*KRAS G12C* mutation positive tumors	*ERBB2 (HER2)* mutation positive tumors
– Pembrolizumab – Atezolizumab – Nivolumab + ipilimumab – Cemiplimab – Tremelimumab + durvalumab	– Capmatinib – Crizotinib – Tepotinib	– Selpercatinib – Cabozantinib – Pralsetinib	– Sotorasib – Adagrasib	– Fam-trastuzumab deruxtecan-nxki – Ado-trastuzumab emtansine

IV. Renewal Criteria [Δ 1,2,6,9-12,17-29,39-41,46,49]

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/rash, 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:
  - Colorectal Cancer *(subsequent therapy/disease progression)*
  - Appendiceal Adenocarcinoma *(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 (see below).*
  - Cutaneous Melanoma *(adjuvant therapy in combination with nivolumab)*
  - Hepatocellular Carcinoma
  - Renal Cell Carcinoma
  - Small Bowel Adenocarcinoma
  - Ampullary Adenocarcinoma
  - Uveal Melanoma
- For the following indications, patient has not exceeded a maximum of two (2) years of therapy:
  - Bone Cancer
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer
  - Kaposi Sarcoma
  - Malignant Peritoneal Mesothelioma
  - Malignant Pleural Mesothelioma
  - Non-Small Cell Lung Cancer

Cutaneous Melanoma (re-induction therapy)

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

Cutaneous Melanoma (single agent 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.
- Patients diagnosed with Renal Cell Carcinoma with clear cell histology who have received previous immuno-oncology therapy may be eligible for treatment with ipilimumab as subsequent therapy and will be evaluated on a case-by-case basis.

V. Dosage/Administration Δ [1,5,6,8-12,17-29,31,33,34,38-42,44,46,49]

Indication	Dose
Renal Cell Carcinoma (RCC), Small Bowel Adenocarcinoma (SBA), & Ampullary Adenocarcinoma	Administer 1 mg/kg intravenously every 3 weeks for a total of 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)
Bone Cancer	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
CNS metastases from Melanoma	Single agent: o Initial: Administer 10 mg/kg intravenously every 3 weeks for 4 doses o Subsequent (starting at week 24): Administer 10 mg/kg intravenously every 12 weeks until disease progression or unacceptable toxicity In combination with nivolumab: o Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)
Colorectal Cancer (CRC) & Appendiceal Adenocarcinoma	Primary/initial treatment o Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab every 2 weeks), until disease progression or unacceptable toxicity Subsequent therapy/disease progression o 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 and Esophagogastric/ Gastroesophageal Junction Cancer	Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab every 2 or 3 weeks) 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) & Malignant Peritoneal Mesothelioma (MPeM)	Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab every 3 weeks) until disease progression or unacceptable toxicity for up to 2 years
Cutaneous Melanoma *(excluding adjuvant therapy)*	Single agent or in combination with nivolumab: o 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: o 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)	**Single agent** o Initial: Administer 10 mg/kg intravenously every 3 weeks for up to a maximum of 4 doses o Maintenance: Administer 10 mg/kg intravenously every 12 weeks for up to 3 years **In combination with nivolumab** o Administer 3 mg/kg intravenously every 3 weeks for a maximum of 4 doses (given in combination with nivolumab)
Uveal Melanoma	Single agent: o Administer 3 mg/kg or 10mg/kg intravenously every 3 weeks for 4 doses In combination with nivolumab: o 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: o Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab every 3 weeks), until disease progression or unacceptable toxicity for up to 2 years In combination with nivolumab and platinum-doublet chemotherapy: o 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
Kaposi Sarcoma	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 24 months (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 50 mg/10 mL injection single-dose vial: 00003-2327-xx
- Yervoy 200 mg/40 mL injection single-dose vial: 00003-2328-xx

VII. References

1. Yervoy [package insert]. Princeton, NJ; Bristol Meyers Squib; February 2023. Accessed February 2023.
2. Referenced with permission from the NCCN Drugs & Biologics Compendium (NCCN Compendium®) ipilimumab. 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 February 2023.
3. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Small Cell Lung Cancer. 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 Guidelines, go online to NCCN.org. Accessed February 2023.
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5. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Malignant Pleural Mesothelioma. Version 1.2023. National Comprehensive Cancer Network, 2023. The NCCN Compendium® is a derivative work of the NCCN Guidelines®. NATIONAL COMPREHENSIVE CANCER NETWORK®, NCCN®, and NCCN

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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
C16.0	Malignant neoplasm of cardia
C17.0	Malignant neoplasm of duodenum
C17.1	Malignant neoplasm of jejunum
C17.2	Malignant neoplasm of ileum
C17.3	Meckel's diverticulum, malignant
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

ICD-10	ICD-10 Description
C22.8	Malignant neoplasm of liver, primary, unspecified as to type
C22.9	Malignant neoplasm of liver, not specified as primary or secondary
C24.1	Malignant neoplasm of ampulla of Vater
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
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung
C40.00	Malignant neoplasm of scapula and long bones of unspecified upper limb
C40.01	Malignant neoplasm of scapula and long bones of right upper limb
C40.02	Malignant neoplasm of scapula and long bones of left upper limb
C40.10	Malignant neoplasm of short bones of unspecified upper limb
C40.11	Malignant neoplasm of short bones of right upper limb
C40.12	Malignant neoplasm of short bones of left upper limb
C40.20	Malignant neoplasm of long bones of unspecified lower limb
C40.21	Malignant neoplasm of long bones of right lower limb
C40.22	Malignant neoplasm of long bones of left lower limb
C40.30	Malignant neoplasm of short bones of unspecified lower limb
C40.31	Malignant neoplasm of short bones of right lower limb
C40.32	Malignant neoplasm of short bones of left lower limb
C40.80	Malignant neoplasm of overlapping sites of bone and articular cartilage of unspecified limb
C40.81	Malignant neoplasm of overlapping sites of bone and articular cartilage of right limb
C40.82	Malignant neoplasm of overlapping sites of bone and articular cartilage of left limb
C40.90	Malignant neoplasm of unspecified bones and articular cartilage of unspecified limb
C40.91	Malignant neoplasm of unspecified bones and articular cartilage of right limb
C40.92	Malignant neoplasm of unspecified bones and articular cartilage of left limb

ICD-10	ICD-10 Description
C41.0	Malignant neoplasm of bones of skull and face
C41.1	Malignant neoplasm of mandible
C41.2	Malignant neoplasm of vertebral column
C41.3	Malignant neoplasm of ribs, sternum and clavicle
C41.4	Malignant neoplasm of pelvic bones, sacrum and coccyx
C41.9	Malignant neoplasm of bone and articular cartilage, unspecified
C43.0	Malignant melanoma of lip
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
C45.1	Mesothelioma of peritoneum
C45.2	Mesothelioma of pericardium
C45.7	Mesothelioma of other sites
C45.9	Mesothelioma, unspecified
C46.0	Kaposi's sarcoma of skin
C46.1	Kaposi's sarcoma of soft tissue
C46.2	Kaposi's sarcoma of palate
C46.3	Kaposi's sarcoma of lymph nodes

ICD-10	ICD-10 Description
C46.4	Kaposi's sarcoma of gastrointestinal sites
C46.50	Kaposi's sarcoma of unspecified lung
C46.51	Kaposi's sarcoma of right lung
C46.52	Kaposi's sarcoma of left lung
C46.7	Kaposi's sarcoma of other sites
C46.9	Kaposi's sarcoma, unspecified
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
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
C72.0	Malignant neoplasm of spinal cord
C72.1	Malignant neoplasm of cauda equina
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
D19.1	Benign neoplasm of mesothelial tissue of peritoneum
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
Z85.09	Personal history of malignant neoplasm of other digestive organs
Z85.118	Personal history of other malignant neoplasm of bronchus and lung

ICD-10	ICD-10 Description
Z85.820	Personal history of malignant melanoma of skin
Z85.830	Personal history of malignant neoplasm of bone

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.
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

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200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
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ማስታወሻ: የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያግዝዎት ተዘጋጀተዋል፡ ወደ ሚከተለው ቁጥር ይደውሉ 1.800.940.5049 (መስማት ለተሳናቸው: 763.847.4013).

ဟသျှဉ်ဟသး– နမ့်ကတိ၊ ကညီ ကျိာ်အယိ, နမၤန့် ကျိာ်အတ်မၤစၢၤလ၊ တလၫ်ဘူဉ်လၫ်စ့၊ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

ACHTUNG: Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 1.800.940.5049 (TTY: 763.847.4013).

ប្រយ័ត្ន៖ បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតឈ្នួល គឺអាចមានសំរាប់បំរើអ្នក។ ចូរ ទូរស័ព្ទ 1.800.940.5049 (TTY: 763.847.4013).។

ملحوظة: إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 1.800.940.5049 (رقم هاتف الصم والبكم: 763.847.4013).

ATTENTION : Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 1.800.940.5049 (TTY: 763.847.4013).

주의: 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 1.800.940.5049 (TTY: 763.847.4013). 번으로 전화해 주십시오.

PAUNAWA: Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 1.800.940.5049 (TTY: 763.847.4013).

PreferredOne Insurance Company Nondiscrimination Notice

PreferredOne Insurance Company ("PIC") complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, or sex. PIC does not exclude people or treat them differently because of race, color, national origin, age, disability, or sex.

PIC:
Provides free aids and services to people with disabilities to communicate effectively with us, such as:

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

Provides free language services to people whose primary language is not English, such as:

- Qualified interpreters
- Information written in other languages

If you need these services, contact a Grievance Specialist.

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

Grievance Specialist
PreferredOne Insurance Company
PO Box 59212
Minneapolis, MN 55459-0212
Phone: 1.800.940.5049 (TTY: 763.847.4013)
Fax: 763.847.4010
customerservice@preferredone.com

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

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

U.S. Department of Health and Human Services
200 Independence Avenue, SW
Room 509F, HHH Building
Washington, D.C. 20201
1-800-368-1019, 800-537-7697 (TDD)

Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html.

Language Assistance Services

ATTENTION: If you do not speak English, language assistance services, free of charge, are available to you. Call 1.800.940.5049 (TTY: 763.847.4013).

ATENCIÓN: si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 1.800.940.5049 (TTY: 763.847.4013).

LUS CEEV: Yog tias koj hais lus Hmoob, cov kev pab txog lus, muaj kev pab dawb rau koj. Hu rau 1.800.940.5049 (TTY: 763.847.4013).

XIYYEEFFANNAA: Afaan dubbattu Oroomiffa, tajaajila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 1.800.940.5049 (TTY: 763.847.4013).

CHÚ Ý: Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 1.800.940.5049 (TTY: 763.847.4013).

注意：如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 1.800.940.5049 (TTY: 763.847.4013)。

ВНИМАНИЕ: Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 1.800.940.5049 (телетайп: 763.847.4013).

ໂປດຊາບ: ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ເສັຽຄ່າ, ແມ່ນມີພ້ອມໃຫ້ທ່ານ. ໂທຣ 1.800.940.5049 (TTY: 763.847.4013).

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ဟသူဉ်ဟ်သး– နမ့ါကတိၤ ကညီ ကျိာ်အယိ, နမၤန့ါ ကျိာ်အတ၊်မၤစၢၤလၢ တလၢာ်ဘူဉ်လၢာ်စ့ၤ နီတမံၤဘဉ်သ့နှဉ်လီၤ. ကိး 1.800.940.5049 (TTY: 763.847.4013).

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