**Yervoy® (ipilimumab)**
(Intravenous)

Last Review Date: 03/31/2023  
Date of Origin: 07/01/2020  
Dates Reviewed: 07/2020, 10/2020, 12/2020, 04/2021, 07/2021, 10/2021, 01/2022, 04/2022, 07/2022, 10/2022, 01/2023, 04/2023

I. **Length of Authorization**

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)*
  - 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
  - Uveal Melanoma

- The following indications may be renewed up to a maximum of two (2) years of therapy:
  - Kaposi Sarcoma
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer
  - 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:**
B. Max Units (per dose and over time) [HCPCS Unit]:

<table>
<thead>
<tr>
<th>Indication</th>
<th>Billable Units (BU)</th>
<th>Per unit time (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>HCC</td>
<td>350 BU</td>
<td>21 days x 4 doses</td>
</tr>
<tr>
<td>Cutaneous Melanoma, CNS metastases</td>
<td>Initial: 1150 BU</td>
<td>Initial: 21 days x 4 doses</td>
</tr>
<tr>
<td></td>
<td>Followed by: 1150 BU</td>
<td>Followed by: 84 days</td>
</tr>
<tr>
<td>Uveal Melanoma</td>
<td>1150 BU</td>
<td>21 days x 4 doses</td>
</tr>
<tr>
<td>RCC</td>
<td>150 BU</td>
<td>21 days x 4 doses</td>
</tr>
<tr>
<td>CRC, Esophageal and Esophagogastric/Gastroesophageal Junction Cancer, MPM, NSCLC, Kaposi Sarcoma</td>
<td>150 BU</td>
<td>42 days</td>
</tr>
</tbody>
</table>

III. Initial Approval Criteria

Coverage is provided in the following conditions:

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

Central Nervous System (CNS) Cancer ‡ 3,4,8,10,11,27,82e

- 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

Colorectal Cancer (CRC) † 1,2,19,31,42,85e-87e,94e

- 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.) A; 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 †‡; OR
  - Used as primary treatment: AND
    - Used for unresectable (or medically inoperable) 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 † 1,2,45,105e**
- Patient has esophageal squamous cell carcinoma (ESCC); **AND**
- Patient has not previously received treatment with a checkpoint inhibitor (e.g., nivolumab, pembrolizumab, etc.); **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) † 1,2,30e,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

**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

**Malignant Pleural Mesothelioma (MPM)** **† ‡ 1,2,5,25,36,34,37**
- Used in combination with nivolumab; **AND**
  - Used as subsequent therapy (if not administered first-line); **AND**
    - Patient previously received platinum-containing chemotherapy; **OR**
o Used as first-line therapy in patients with medically inoperable or unresectable disease

**Cutaneous Melanoma † ‡ ⚫ 1,2,6,17,43,5a,8e,11a,13e,21e,23e,99e,100e**

- Used as first-line therapy for unresectable or metastatic* disease †: AND
  o Patient is at least 12 years of age: AND
  o Used as a single agent or in combination with nivolumab: OR
- Used as subsequent therapy for unresectable or metastatic* disease: AND
  o 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
  o 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 adjuvant treatment: AND
  o Used as a single agent: 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 †: OR
  o 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, 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 nivolumab as first-line therapy

Non-Small Cell Lung Cancer (NSCLC) † † 1,12,16,19,23,35e-37e,39e-69e,110e

- 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, NTRK1/2/3 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 testφ, 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.); **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, 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;
  **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.

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/CompanionDiagnostics

FDA approved indication(s); † Compendia recommended indication; ✔ 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 | Alectinib | Ceritinib | Dabrafenib | Larotrectinib |
| Erlotinib | Brigatinib | Crizotinib | trametinib | Entrectinib |
| Dacomitinib | Ceritinib | Entrectinib | Lorlatinib | |
| Gefitinib | Crizotinib | Lorlatinib | | |
| Osimertinib | Amivantamab (exon-20 insertion) | | | |
| Mobocertinib (exon-20 insertion) | | | | |
| 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 | Capmatinib | Selpercatinib | Sotorasib | Fam-trastuzumab deruxtecan-nkix |
| Atezolizumab | Crizotinib | Cabozantinib | Adagrasib | Ado-trastuzumab emtansine |
| Nivolumab + ipilimumab | Tepotinib | Pralsetinib | | |
| Cemiplimab | | | | |
| Tremelimumab + durvalumab | | | | |

Moda Health Plan, Inc. Medical Necessity Criteria

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Renewal Criteria

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)
  - 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
  - Uveal Melanoma

- For the following indications, patient has not exceeded a maximum of two (2) years of therapy:
  - Esophageal and Esophagogastric/Gastroesophageal Junction Cancer
  - Kaposi Sarcoma
  - 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
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

<table>
<thead>
<tr>
<th>Indication</th>
<th>Dose</th>
</tr>
</thead>
<tbody>
<tr>
<td>Renal Cell Carcinoma (RCC)</td>
<td>Administer 1 mg/kg intravenously every 3 weeks for a total of 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)</td>
</tr>
<tr>
<td>CNS metastases from Melanoma</td>
<td>Single agent:</td>
</tr>
<tr>
<td></td>
<td>o Initial: Administer 10 mg/kg intravenously every 3 weeks for 4 doses</td>
</tr>
<tr>
<td></td>
<td>o Subsequent (starting at week 24): Administer 10 mg/kg intravenously every 12 weeks until disease progression or unacceptable toxicity</td>
</tr>
<tr>
<td></td>
<td>In combination with nivolumab:</td>
</tr>
<tr>
<td></td>
<td>o Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)</td>
</tr>
<tr>
<td>Colorectal Cancer (CRC)</td>
<td>Primary/initial treatment:</td>
</tr>
<tr>
<td></td>
<td>o Administer 1 mg/kg intravenously every 6 weeks (given in combination with nivolumab every 2 weeks), until disease progression or unacceptable toxicity</td>
</tr>
<tr>
<td></td>
<td>Subsequent therapy/disease progression:</td>
</tr>
<tr>
<td></td>
<td>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)</td>
</tr>
<tr>
<td>Esophageal and Esophagogastric/ Gastroesophageal Junction Cancer</td>
<td>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</td>
</tr>
<tr>
<td>Hepatocellular Carcinoma (HCC)</td>
<td>Administer 3 mg/kg intravenously every 3 weeks for a total of 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)</td>
</tr>
<tr>
<td>Malignant Pleural Mesothelioma (MPM)</td>
<td>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</td>
</tr>
<tr>
<td>Cutaneous Melanoma (excluding adjuvant therapy)</td>
<td>Single agent or in combination with nivolumab:</td>
</tr>
<tr>
<td></td>
<td>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)</td>
</tr>
<tr>
<td></td>
<td>In combination with pembrolizumab as subsequent therapy:</td>
</tr>
<tr>
<td>Condition</td>
<td>Treatment Details</td>
</tr>
<tr>
<td>-----------</td>
<td>-------------------</td>
</tr>
<tr>
<td>Cutaneous Melanoma (adjuvant therapy)</td>
<td><strong>Single agent</strong>&lt;br&gt;o Initial: Administer 10 mg/kg intravenously every 3 weeks for up to a maximum of 4 doses&lt;br&gt;o Maintenance: Administer 10 mg/kg intravenously every 12 weeks for up to 3 years&lt;br&gt;<strong>In combination with nivolumab</strong>&lt;br&gt;o Administer 3 mg/kg intravenously every 3 weeks for a maximum of 4 doses (given in combination with nivolumab)</td>
</tr>
<tr>
<td>Uveal Melanoma</td>
<td><strong>Single agent</strong>&lt;br&gt;o Administer 3 mg/kg or 10 mg/kg intravenously every 3 weeks for 4 doses&lt;br&gt;<strong>In combination with nivolumab</strong>&lt;br&gt;o Administer 3 mg/kg intravenously every 3 weeks for 4 doses (given in combination with nivolumab, then follow with nivolumab monotherapy)</td>
</tr>
<tr>
<td>Non-Small Cell Lung Cancer (NSCLC)</td>
<td><strong>In combination with nivolumab:</strong>&lt;br&gt;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&lt;br&gt;<strong>In combination with nivolumab and platinum-doublet chemotherapy:</strong>&lt;br&gt;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</td>
</tr>
<tr>
<td>Kaposi Sarcoma</td>
<td><strong>In combination with nivolumab:</strong>&lt;br&gt;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)</td>
</tr>
</tbody>
</table>

*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:**<br> 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 (STANDARD)**

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 March 2023.


VIII. References (ENHANCED)

1e. Referenced with permission from the NCCN Clinical Practice Guidelines (NCCN Guidelines®) Melanoma: Cutaneous, Version 3.2022. 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 March 2023.


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(REACH): a randomised, double-blind, multicentre, phase 3 trial. Lancet Oncol. 2015
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with advanced hepatocellular carcinoma (aHCC): Results from CheckMate 040 (abstract). J
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### Appendix 1 – Covered Diagnosis Codes

<table>
<thead>
<tr>
<th>ICD-10</th>
<th>ICD-10 Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C15.3</td>
<td>Malignant neoplasm of upper third of esophagus</td>
</tr>
<tr>
<td>C15.4</td>
<td>Malignant neoplasm of middle third of esophagus</td>
</tr>
<tr>
<td>C15.5</td>
<td>Malignant neoplasm of lower third of esophagus</td>
</tr>
<tr>
<td>C15.8</td>
<td>Malignant neoplasm of overlapping sites of esophagus</td>
</tr>
<tr>
<td>C15.9</td>
<td>Malignant neoplasm of esophagus, unspecified</td>
</tr>
<tr>
<td>C16.0</td>
<td>Malignant neoplasm of cardia</td>
</tr>
<tr>
<td>C17.0</td>
<td>Malignant neoplasm of duodenum</td>
</tr>
<tr>
<td>C17.1</td>
<td>Malignant neoplasm of jejunum</td>
</tr>
<tr>
<td>ICD-10</td>
<td>ICD-10 Description</td>
</tr>
<tr>
<td>--------</td>
<td>--------------------</td>
</tr>
<tr>
<td>C17.2</td>
<td>Malignant neoplasm of ileum</td>
</tr>
<tr>
<td>C17.8</td>
<td>Malignant neoplasm of overlapping sites of small intestine</td>
</tr>
<tr>
<td>C17.9</td>
<td>Malignant neoplasm of small intestine, unspecified</td>
</tr>
<tr>
<td>C18.0</td>
<td>Malignant neoplasm of cecum</td>
</tr>
<tr>
<td>C18.1</td>
<td>Malignant neoplasm of appendix</td>
</tr>
<tr>
<td>C18.2</td>
<td>Malignant neoplasm of ascending colon</td>
</tr>
<tr>
<td>C18.3</td>
<td>Malignant neoplasm of hepatic flexure</td>
</tr>
<tr>
<td>C18.4</td>
<td>Malignant neoplasm of transverse colon</td>
</tr>
<tr>
<td>C18.5</td>
<td>Malignant neoplasm of splenic flexure</td>
</tr>
<tr>
<td>C18.6</td>
<td>Malignant neoplasm of descending colon</td>
</tr>
<tr>
<td>C18.7</td>
<td>Malignant neoplasm of sigmoid colon</td>
</tr>
<tr>
<td>C18.8</td>
<td>Malignant neoplasm of overlapping sites of colon</td>
</tr>
<tr>
<td>C18.9</td>
<td>Malignant neoplasm of colon, unspecified</td>
</tr>
<tr>
<td>C19</td>
<td>Malignant neoplasm of rectosigmoid junction</td>
</tr>
<tr>
<td>C20</td>
<td>Malignant neoplasm of rectum</td>
</tr>
<tr>
<td>C21.8</td>
<td>Malignant neoplasm of overlapping sites of rectum, anus and anal canal</td>
</tr>
<tr>
<td>C22.0</td>
<td>Liver cell carcinoma</td>
</tr>
<tr>
<td>C22.8</td>
<td>Malignant neoplasm of liver, primary, unspecified as to type</td>
</tr>
<tr>
<td>C22.9</td>
<td>Malignant neoplasm of liver, not specified as primary or secondary</td>
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<tr>
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</tr>
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<td>Malignant neoplasm of lower lobe, left bronchus or lung</td>
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<td>C43.22</td>
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<td>Malignant melanoma of anal skin</td>
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ICD-10 | ICD-10 Description
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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
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

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<th>Jurisdiction</th>
<th>Applicable State/US Territory</th>
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<td>Jurisdiction</td>
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<td>Contractor</td>
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<td>First Coast Service Options, Inc.</td>
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