Bevacizumab: Avastin[®]; Mvasi[®]; Zirabev[™]; Alymsys[®]; Vegzelma[®]

(Intravenous)

ONCOLOGY

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I. Length of Authorization ⁸

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

- For Adult CNS Cancers (symptom management), coverage will be provided for twelve (12) weeks and may NOT be renewed.
- For MPM and MPeM in combination with pemetrexed AND either cisplatin or carboplatin, coverage will be provided for up to six (6) cycles and may NOT be renewed.

II. Dosing Limits

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

- 100 mg/4 mL single-dose vial: 3 vials 21 days
- 400 mg/16 mL single-dose vial: 4 vials per 21 days
- B. Max Units (per dose and over time) [HCPCS Unit]:

Oncology indications (J9035/Q5107/Q5118/J9999/Q5126/Q5129):

- <u>Small Bowel Adenocarcinoma/Ampullary Adenocarcinoma</u>:
 - \circ 60 billable units per 14 days
- NSCLC, Cervical Cancer, HCC, Vulvar Cancer, MPM, & MPeM:
 - \circ 170 billable units per 21 days
- <u>All other indications</u>:
 - $\circ \quad 120 \text{ billable units per } 14 \text{ days}$

III. Initial Approval Criteria¹⁻⁵

Coverage is provided in the following conditions:

 Patients must have failed, or have a contraindication, or intolerance to bevacizumab-awwb (Mvasi[™]) OR bevacizumab-bvzr (Zirabev[™]) prior to consideration of another bevacizumab product; AND

• Patient is at least 18 years of age, unless otherwise specified; AND

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Universal Criteria¹⁻⁵

- Patient has no recent history of hemoptysis (i.e., the presence of ≥2.5 mL of blood in sputum);
 AND
- Patient must not have had a surgical procedure within the preceding 28 days or have a surgical wound that has not fully healed; **AND**

Ampullary Adenocarcinoma ‡⁶

- Used in combination with a fluoropyrimidine- (e.g., 5-fluorouracil/5-FU or capecitabine) based regimen for intestinal type disease; **AND**
 - \circ Used as first-line therapy for unresectable localized or metastatic disease; OR
 - Used as subsequent therapy for disease progression; AND
 - Patient has poor performance status (ECOG PS 2); OR
 - Patient has good performance status (ECOG 0-1, with good biliary drainage and adequate nutritional intake) and received prior oxaliplatin-based therapy

Adult Central Nervous System (CNS) Cancers † [‡]^{1-6,8,27,28}

- Used as single-agent short-course therapy for symptom management related to radiation necrosis, poorly controlled vasogenic edema, or mass effect; **AND**
 - \circ Patient has a diagnosis of one of the following CNS cancers \ddagger
 - Circumscribed Glioma
 - Primary CNS Lymphoma
 - Meningiomas
 - Brain or Spine metastases
 - Medulloblastoma
 - Glioblastoma/Gliosarcoma/H3-mutated high grade glioma
 - IDH-mutant Astrocytoma (WHO Grade 2-4)
 - IDH-mutant, 1p19q codeleted Oligodendroglioma (WHO Grade 2 or 3)
 - Intracranial or Spinal Ependymoma (excluding subependymoma); OR
- Used for recurrent or progressive disease; AND
 - Patient has a diagnosis of one of the following CNS cancers:
 - IDH-mutant, 1p19q codeleted Oligoden
droglioma (WHO Grade 3) $\ddagger \Phi$
 - Glioblastoma/Gliosarcoma/H3-mutated high grade glioma **† ‡**
 - IDH-mutant Astrocytoma (WHO Grade 3 or 4); AND
 - Used as a single agent; **OR**
 - Used in combination with carmustine, lomustine, or temozolomide; AND
 - > Patient has failed bevacizumab monotherapy; OR
 - Used as a single agent for Intracranial or Spinal Ependymoma (excluding subependymoma) after prior radiation therapy \$; OR

 Used as a single agent for surgically inaccessible Meningioma when radiation is not possible ‡

Cervical Cancer † [‡] ^{1-6,30,49}

- Patient has persistent, recurrent, or metastatic disease; AND
 - o Disease has adenocarcinoma, adenosquamous, or squamous cell carcinoma histology; AND
 - Used in combination with paclitaxel AND either cisplatin, carboplatin, or topotecan;
 OR
 - Used in combination with pembrolizumab, paclitaxel, AND cisplatin or carboplatin; AND
 - ➤ Tumor expresses PD-L1 (Combined Positive Score [CPS] ≥1) as determined by an FDA-approved or CLIA compliant test \$; OR
 - Used as a single agent as subsequent therapy; **OR**
 - Patient has small cell neuroendocrine carcinoma of the cervix (NECC); AND
 - Used in combination with paclitaxel and topotecan; OR
 - Used as a single agent as subsequent therapy

Colorectal Cancer (CRC) † ‡ 1-6,19-24

- Will not be used as part of adjuvant treatment; AND
 - Used in combination with a fluoropyrimidine- (e.g., 5-fluorouracil/5-FU or capecitabine) or irinotecan-based regimen as first-line or subsequent therapy for metastatic, unresectable (or medically inoperable), or advanced disease; OR
 - Used in combination with a fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatinbased regimen (not used first line) as second-line therapy for metastatic disease that has progressed on a first-line bevacizumab-containing regimen **†**; **OR**
 - Used in combination with trifluridine and tipiracil as subsequent therapy for advanced or metastatic disease after progression on all available regimens

Appendiceal Adenocarcinoma – Colon Cancer ‡ 6,47

- Used as initial therapy for advanced or metastatic disease; AND
 - Used in combination with a fluoropyrimidine- (e.g., 5-fluorouracil/5-FU or capecitabine) based regimen; OR
- Used as subsequent therapy for progression of advanced or metastatic disease; AND
 - Used in combination with a fluoropyrimidine- (e.g., 5-fluorouracil/5-FU or capecitabine) or irinotecan-based regimen following previous oxaliplatin- irinotecan- and/or fluoropyrimidine-based therapy; OR
 - Used in combination with trifluridine and tipiracil after progression on all available regimens

Endometrial Carcinoma (Uterine Neoplasms) ‡6

- Used as a single agent for recurrent or metastatic disease that has progressed on prior cytotoxic chemotherapy; \mathbf{OR}
- Used in combination with carboplatin and paclitaxel for advanced and recurrent disease

Hepatocellular Carcinoma (HCC) † ‡ Φ ^{1,6,16,17}

- Used as first-line therapy in combination with atezolizumab; AND
- Patient has Child-Pugh Class A or Class B disease; AND
 - \circ $\;$ Patient has unresectable disease and is not a transplant candidate; \mathbf{OR}
 - Patient has liver-confined disease that is inoperable by performance status, comorbidity, or with minimal or uncertain extrahepatic disease; **OR**
 - o Patient has metastatic disease or extensive liver tumor burden

Malignant Peritoneal* Mesothelioma (MPeM) ± 6,44

- Used as first-line therapy; AND
 - Used in combination with pemetrexed AND either cisplatin or carboplatin (if cisplatin ineligible); AND
 - Patient has unresectable diffuse disease; **OR**
 - Patient has unresectable recurrent benign multicystic or well-differentiated papillary disease; OR
- Used as subsequent therapy; AND
 - Used in combination with pemetrexed AND either cisplatin or carboplatin (if cisplatin ineligible); AND
 - Immunotherapy was administered as first-line treatment; **OR**
 - \circ $\:$ Used in combination with atezolizumab; AND $\:$
 - Patient has not received previous therapy with immune checkpoint inhibitors (e.g., nivolumab, pembrolizumab, durvalumab, avelumab, cemiplimab, dostarlimab, nivolumab/relatlimab-rmbw, etc.)

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

Malignant Pleural** Mesothelioma (MPM) ‡ 6,39

- Used as first-line therapy; AND
 - $\circ~$ Used in combination with pemetrexed AND either cisplatin or carboplatin (if cisplatin ineligible) for unresectable disease; \mathbf{OR}
- Used as subsequent therapy; AND
 - Used in combination with pemetrexed AND either cisplatin or carboplatin (if cisplatin ineligible); AND
 - o Immunotherapy was administered as first-line treatment

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

Non-Squamous Non-Small Cell Lung Cancer (NSCLC) † 1-6,12,14,15,25,26

- Used for recurrent, advanced, or metastatic disease (excluding locoregional recurrence or symptomatic local disease with no evidence of disseminated disease) or mediastinal lymph node recurrence with prior radiation therapy; **AND**
 - Used as first-line therapy; AND
 - Used in combination with erlotinib for EGFR exon 19 deletion or exon 21 L858R mutations; OR
 - 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 expression < 1%
 - PD-L1 expression positive (PD-L1 ≥ 1%) tumors that are negative for actionable molecular biomarkers*
 - 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); AND
 - > Used in combination with one of the following:
 - Carboplatin and paclitaxel †
 - Pemetrexed and either carboplatin or cisplatin in patients with contraindications¥ to PD-1 or PD-L1 inhibitors
 - Atezolizumab, carboplatin, and paclitaxel; OR
 - Used as subsequent therapy in patients with a PS 0-1; AND
 - Used for one of the following:
 - EGFR exon 19 deletion or exon 21 L858R mutation, EGFR S768I, L861Q, and/or G719X mutation, ALK rearrangement, or ROS1 rearrangement positive tumors AND patient received prior targeted therapy§ for those aberrations
 - BRAF V600E mutation, NTRK1/2/3 gene fusion, MET exon 14 skipping mutation, or RET rearrangement positive tumors
 - ➢ PD-L1 expression positive (PD-L1 ≥ 1%) tumors that are negative for actionable molecular biomarkers* after prior PD-1/PD-L1 inhibitor therapy but no prior platinum-containing chemotherapy; AND
 - Used in combination with one of the following:
 - Carboplatin and paclitaxel in patients with contraindications¥ to PD-1 or PD-L1 inhibitors
 - Pemetrexed and either carboplatin or cisplatin in patients with contraindications¥ to PD-1 or PD-L1 inhibitors
 - Atezolizumab, carboplatin, and paclitaxel (excluding use in patients who have received prior PD-1/PD-L1 inhibitor therapy), OR
 - Used as continuation maintenance therapy in patients who achieved a tumor response or stable disease after first-line systemic therapy; AND
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- Used as a single agent (bevacizumab must have been included in the first-line regimen); **OR**
- Used in combination with pemetrexed following a first-line bevacizumab/pemetrexed/platinum chemotherapy regimen; OR
- Used in combination with atezolizumab following a first-line atezolizumab/carboplatin/paclitaxel/bevacizumab regimen; **OR**
- Used as continuation of therapy following disease progression on erlotinib with bevacizumab; AND
 - Patient has asymptomatic disease, symptomatic brain lesions, or symptomatic systemic limited progression; AND
 - Patient has T790M negative disease

* Note: Actionable molecular genomic biomarkers include EGFR, KRAS, ALK, ROS1, BRAF, NTRK1/2/3, MET, 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.

¥ Note: Contraindications for treatment with PD-1/PD-L1 inhibitors may include active or previously documented autoimmune disease and/or current use of immunosuppressive agents, and some oncogenic drivers (i.e., EGFR exon 19 deletion or exon 21 L858R, ALK rearrangements) have been shown to be associated with less benefit from PD-1/PD-L1 inhibitors.

Ovarian, Fallopian Tube, and Primary Peritoneal Cancer † $\pm \Phi$ ^{1-6,13,31-34}

- Patient has malignant stage II-IV sex cord-stromal tumors **‡**; **AND**
 - Used as a single agent for clinically relapsed disease; **OR**
- Patient has epithelial* ovarian, fallopian tube, or primary peritoneal cancer **†**; AND
 - Patient has persistent or recurrent disease; AND
 - Bevacizumab has not been used previously; AND
 - Patient is not experiencing an immediate biochemical relapse (i.e., rising CA-125 without radiographic evidence of disease); AND
 - > Patient has platinum-sensitive disease; AND
 - Used as a single agent; **OR**
 - Used in combination with carboplatin AND either gemcitabine, paclitaxel
 † or liposomal doxorubicin; OR
 - Patient has platinum-resistant disease; AND
 - Used as a single agent; OR
 - Used in combination with one of the following: oral cyclophosphamide, liposomal doxorubicin, paclitaxel, or topotecan *†*; OR
 - Used in combination with paclitaxel and carboplatin for rising CA-125 levels or clinical relapse in patients who have received no prior chemotherapy (*mucinous, clear cell, carcinosarcoma, endometrioid, and serous histology only*); **OR**

- Used as maintenance therapy; AND
 - Used for stage II-IV disease following primary therapy including bevacizumab; AND
 - Used as a single agent in patients that are BRCA1/2 wild-type or unknown AND homologous recombination (HR) proficient, HR deficient, or status unknown (grade 2/3 endometrioid and high-grade serous histology only); OR
 - > Used in combination with olaparib; AND
 - Patient is BRCA1/2 wild-type or unknown AND HR deficient (grade 2/3 endometrioid and high-grade serous histology only); OR
 - Patient has a germline or somatic BRCA1/2 mutation (grade 2/3 endometrioid, high-grade serous, clear cell, carcinosarcoma histology only), OR
 - Used as a single agent following recurrence therapy with chemotherapy plus bevacizumab for platinum-sensitive disease; **OR**
 - Used in combination with carboplatin AND paclitaxel or docetaxel for stable disease following neoadjuvant therapy as continued treatment *(endometrioid and serous histology only)*; OR
- Used as neoadjuvant therapy in combination with carboplatin AND paclitaxel or docetaxel *(endometrioid and serous histology only)*; **AND**
 - Patient is a poor surgical candidate or has a low likelihood of optimal cytoreduction;
 OR
- Used as adjuvant therapy in combination with carboplatin AND paclitaxel or docetaxel; AND
 - Patient has pathologic stage II-IV disease (mucinous, clear cell, carcinosarcoma, borderline epithelial, endometrioid, and serous histology only); OR
 - Used after interval debulking surgery (IDS) in patients with a response or stable disease to neoadjuvant therapy *(endometrioid and serous histology only)*; AND
 - Patient is a poor surgical candidate or has a low likelihood of optimal cytoreduction

* Epithelial subtypes include serous, endometrioid, carcinosarcoma (malignant mixed Müllerian tumors [MMMTs] of the ovary), clear cell, mucinous, and borderline epithelial tumors (also known as low malignant potential [LMP] tumors).

Pediatric Central Nervous System (CNS) Cancers ‡ ^{2,47}

- Patient is ≤ 18 years of age; **AND**
- Patient has diffuse high-grade glioma; AND
- Used for palliation of recurrent or progressive disease (excluding oligodendroglioma, IDHmutant and 1p/19q co-deleted or astrocytoma IDH-mutant)

Renal Cell Carcinoma (RCC) † Φ ^{1-6,29}

• Used in combination with interferon alfa for metastatic disease **†**; **OR**

- Patient has relapsed or metastatic disease with non-clear cell histology; AND
 - Used as a single agent **‡**; **OR**
 - Used in combination with everolimus **‡**; **OR**
 - Used in combination with erlotinib for advanced papillary disease including hereditary leiomyomatosis and renal cell carcinoma (HLRCC)-associated RCC **‡**

Small Bowel Adenocarcinoma ‡ 6,18

- Patient has advanced or metastatic disease; AND
- Used in combination with a fluoropyrimidine-based regimen

Soft Tissue Sarcoma ‡⁶

- Used as a single agent for angiosarcoma; **OR**
- Used in combination with temozolomide for solitary fibrous tumor

Vulvar Cancer ‡ 6

- Used in combination with paclitaxel and cisplatin; AND
- Patient has squamous cell carcinoma or adenocarcinoma; AND
- Patient has unresectable, locally advanced, metastatic, or recurrent disease
- ♦ If confirmed using an FDA-approved assay <u>http://www.fda.gov/companiondiagnostics</u>

FDA Approved Indication(s); Compendia Recommended Indication(s); Orphan Drug

§ Genomic Aberration/Mutational Driver Targeted Therapies ¹² (Note: <i>not all inclusive, refer to guidelines for appropriate use</i>)				
Sensitizing <i>EGFR</i> mutation-positive tumors	ALK rearrangement- positive tumors	<i>ROS1</i> rearrangement- positive tumors	<i>BRAF</i> V600E-mutation positive tumors	<i>NTRK1/2/3</i> gene fusion positive tumors
 Afatinib Erlotinib Dacomitinib Gefitinib Osimertinib Amivantamab <i>(exon-20 insertion)</i> Mobocertinib <i>(exon-20 insertion)</i> 	– Alectinib – Brigatinib – Ceritinib – Crizotinib – Lorlatinib	– Ceritinib – Crizotinib – Entrectinib – Lorlatinib	 Dabrafenib ± trametinib Vemurafenib 	– Larotrectinib – Entrectinib
PD-L1 tumor expression ≥ 1%	MET exon-14 skipping mutations	<i>RET</i> 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

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IV. Renewal Criteria ^{1-6,8}

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**
- Disease response with treatment as defined by stabilization of disease or decrease in size of tumor or tumor spread; **AND**
- Absence of unacceptable toxicity from the drug. Examples of unacceptable toxicity include: gastrointestinal perforations and fistulae, surgical/wound healing complications, necrotizing fasciitis, hemorrhage, arterial and venous thromboembolic events (ATE & VTE), uncontrolled hypertension, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome, proteinuria, severe infusion-related reactions, ovarian failure, congestive heart failure (CHF), etc.; **AND**

Adult CNS Cancers – symptom management (short-course therapy):

• Coverage may NOT be renewed

Adult CNS Cancers – Oligodendroglioma, Glioblastoma, or Astrocytoma (in combination with carmustine, lomustine, or temozolomide):

• Refer to Section III for criteria

Colorectal Cancer (after first-line bevacizumab-containing regimen):

• Refer to Section III for criteria

MPeM (combination therapy with atezolizumab):

• Refer to Section III for criteria

MPM and MPeM (combination therapy with pemetrexed AND either cisplatin or carboplatin):

• Patient has not exceeded a maximum of six (6) cycles.

Non-Squamous Non-Small Cell Lung Cancer (maintenance therapy OR continuation therapy in combination with erlotinib):

• Refer to Section III for criteria

Ovarian Cancer (maintenance therapy):

• Refer to Section III for criteria

V. Dosage/Administration ^{1-4,7,8,13,18,30,36,37,39-48}

Indication	Dose
CRC & Appendiceal	Administer 5 to 10 mg/kg intravenously every 2 weeks <u>OR</u> 7.5 mg/kg
Adenocarcinoma	intravenously every 3 weeks until disease progression or unacceptable toxicity.

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Small Bowel Adenocarcinoma & Ampullary	Administer 5 mg/kg intravenously every 2 weeks <u>OR</u> 7.5 mg/kg intravenously every 3 weeks until disease progression or unacceptable toxicity.
Adenocarcinoma	
NSCLC, Cervical Cancer, HCC, Vulvar Cancer	Administer 15 mg/kg intravenously every 3 weeks until disease progression or unacceptable toxicity.
CNS Cancers	 For disease treatment: Administer 10 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity. For symptom management: Administer 5 to 10 mg/kg intravenously every 2 weeks up to 12 weeks duration.
RCC	Administer 10 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity.
MPM	Administer 15 mg/kg intravenously every 3 weeks in combination with pemetrexed AND either cisplatin or carboplatin for up to 6 cycles.
MPeM	 In combination with pemetrexed AND either cisplatin or carboplatin: Administer 15 mg/kg intravenously every 3 weeks for up to 6 cycles. In combination with atezolizumab: Administer 15 mg/kg intravenously every 3 weeks until disease progression or unacceptable toxicity.
Ovarian, Fallopian Tube, and Primary Peritoneal Cancer	Administer 5 to 10 mg/kg intravenously every 2 weeks <u>OR</u> 7.5 to 15 mg/kg intravenously every 3 weeks until disease progression or unacceptable toxicity.
Pediatric CNS Cancers	Administer 10 mg/kg intravenously every 2 weeks until disease progression or unacceptable toxicity.
All Other Indications	Administer 5 to 10 mg/kg intravenously every 2 weeks <u>OR</u> 7.5 to 15 mg/kg intravenously every 3 weeks until disease progression or unacceptable toxicity.

VI. Billing Code/Availability Information

HCPCS Code(s):

- J9035 Injection, bevacizumab, 10 mg; 1 billable unit = 10 mg
- Q5107 Injection, bevacizumab-awwb, biosimilar, (mvasi), 10 mg; 1 billable unit = 10 mg
- Q5118 Injection, bevacizumab-bvzr, biosimilar, (zirabev), 10 mg; 1 billable unit = 10 mg
- Q5126 Injection, bevacizumab-maly, biosimilar, (alymsys), 10 mg; 1 billable unit = 10 mg
- Q5129 Injection, bevacizumab-adcd, biosimilar, (vegzelma), 10 mg; 1 billable unit = 10 mg

NDC(s):

- Avastin single-dose vial, 100 mg/4 mL solution for injection: 50242-0060-xx
- Avastin single-dose vial, 400 mg/16 mL solution for injection: 50242-0061-xx
- Mvasi single-dose vial, 100 mg/4 mL solution for injection: 55513-0206-xx

- Mvasi single-dose vial, 400 mg/16 mL solution for injection: 55513-0207-xx
- Zirabev single-dose vial, 100 mg/4 mL solution for injection: 00069-0315-xx
- Zirabev single-dose vial, 400 mg/16 mL solution for injection: 00069-0342-xx
- Alymsys single-dose vial, 100 mg/4 mL solution for injection: 70121-1754-xx
- Alymsys single-dose vial, 400 mg/16 mL solution for injection: 70121-1755-xx
- Vegzelma single-dose vial, 100 mg/4 mL solution for injection: 72606-0011-xx
- Vegzelma single-dose vial, 400 mg/16 mL solution for injection: 72606-0012-xx

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ICD-10	ICD-10 Description	
C17.0	Malignant neoplasm duodenum	
C17.1	Malignant neoplasm jejunum	
C17.2	Malignant neoplasm ileum	
C17.3	Meckel's diverticulum, malignant	
C17.8	Malignant neoplasm of overlapping sites of small intestines	
C17.9	Malignant neoplasm of small intestine, unspecified	
C18.0	Malignant neoplasm of cecum	
C18.1	Malignant neoplasm of appendix	
C18.2	Malignant neoplasm of ascending colon	
C18.3	Malignant neoplasm of hepatic flexure	
C18.4	Malignant neoplasm of transverse colon	
C18.5	Malignant neoplasm of splenic flexure	
C18.6	Malignant neoplasm of descending colon	
C18.7	Malignant neoplasm of sigmoid colon	
C18.8	Malignant neoplasm of overlapping sites of large intestines	
C18.9	Malignant neoplasm of colon, unspecified	
C19	Malignant neoplasm of rectosigmoid junction	
C20	Malignant neoplasm of rectum	
C21.8	Malignant neoplasm of overlapping sites of rectum, anus and anal canal	
C22.0	Liver cell carcinoma	
C22.3	Angiosarcoma of the liver	
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	

Appendix 1 – Covered Diagnosis Codes

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ICD-10	ICD-10 Description		
C34.02	Malignant neoplasm of left main bronchus		
C34.10	Malignant neoplasm of upper lobe, unspecified bronchus or lung		
C34.11	Malignant neoplasm of upper lobe, right bronchus or lung		
C34.12	Malignant neoplasm of upper lobe, left bronchus or lung		
C34.2	Malignant neoplasm of middle lobe, bronchus or lung		
C34.30	Malignant neoplasm of lower lobe, unspecified bronchus or lung		
C34.31	Malignant neoplasm of lower lobe, right bronchus or lung		
C34.32	Malignant neoplasm of lower lobe, left bronchus or lung		
C34.80	Malignant neoplasm of overlapping sites of unspecified bronchus or lung		
C34.81	Malignant neoplasm of overlapping sites of right bronchus and lung		
C34.82	Malignant neoplasm of overlapping sites of left bronchus and lung		
C34.90	Malignant neoplasm of unspecified part of unspecified bronchus or lung		
C34.91	Malignant neoplasm of unspecified part of right bronchus or lung		
C34.92	Malignant neoplasm of unspecified part of left bronchus or lung		
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		
C48.0	Malignant neoplasm of retroperitoneum		
C48.1	Malignant neoplasm of specified parts of peritoneum		
C48.2	Malignant neoplasm of peritoneum, unspecified		
C48.8	Malignant neoplasm of overlapping sites of retroperitoneum and peritoneum		
C49.0	Malignant neoplasm of connective and soft tissue of head, face and neck		
C49.10	Malignant neoplasm of connective and soft tissue of unspecified upper limb, including shoulder		
C49.11	Malignant neoplasm of connective and soft tissue of right upper limb including shoulder		
C49.12	Malignant neoplasm of connective and soft tissue of left upper limb, including shoulder		
C49.20	Malignant neoplasm of connective and soft tissue of unspecified lower limb, including hip		
C49.21	Malignant neoplasm of connective and soft tissue of right lower limb, including hip		
C49.22	Malignant neoplasm of connective and soft tissue of left lower limb, including hip		
C49.3	Malignant neoplasm of connective and soft tissue of thorax		
C49.4	Malignant neoplasm of connective and soft tissue of abdomen		
C49.5	Malignant neoplasm of connective and soft tissue of pelvis		
C49.6	Malignant neoplasm of connective and soft tissue of trunk, unspecified		
C49.8	Malignant neoplasm of overlapping sites of connective and soft tissue		
C49.9	Malignant neoplasm of connective and soft tissue, unspecified		
C51.0	Malignant neoplasm of labium majus		

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ICD-10	ICD-10 Description	
C51.1	Malignant neoplasm of labium minus	
C51.2	Malignant neoplasm of clitoris	
C51.8	Malignant neoplasm of overlapping sites of vulva	
C51.9	Malignant neoplasm of vulva, unspecified	
C53.0	Malignant neoplasm of endocervix	
C53.1	Malignant neoplasm of exocervix	
C53.8	Malignant neoplasm of overlapping sites of cervix uteri	
C53.9	Malignant neoplasm of cervix uteri, unspecified	
C54.0	Malignant neoplasm of isthmus uteri	
C54.1	Malignant neoplasm of endometrium	
C54.2	Malignant neoplasm of myometrium	
C54.3	Malignant neoplasm of fundus uteri	
C54.8	Malignant neoplasm of overlapping sites of corpus uteri	
C54.9	Malignant neoplasm of corpus uteri, unspecified	
C55	Malignant neoplasm of uterus, part unspecified	
C56.1	Malignant neoplasm of right ovary	
C56.2	Malignant neoplasm of left ovary	
C56.3	Malignant neoplasm of bilateral ovaries	
C56.9	Malignant neoplasm of unspecified ovary	
C57.00	Malignant neoplasm of unspecified fallopian tube	
C57.01	Malignant neoplasm of right fallopian tube	
C57.02	Malignant neoplasm of left fallopian tube	
C57.10	Malignant neoplasm of unspecified broad ligament	
C57.11	Malignant neoplasm of right broad ligament	
C57.12	Malignant neoplasm of left broad ligament	
C57.20	Malignant neoplasm of unspecified round ligament	
C57.21	Malignant neoplasm of right round ligament	
C57.22	Malignant neoplasm of left round ligament	
C57.3	Malignant neoplasm of parametrium	
C57.4	Malignant neoplasm of uterine adnexa, unspecified	
C57.7	Malignant neoplasm of other specified female genital organs	
C57.8	Malignant neoplasm of overlapping sites of female genital organs	
C57.9	Malignant neoplasm of female genital organ, unspecified	
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	

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ICD-10	ICD-10 Description	
C65.2	Malignant neoplasm of left renal pelvis	
C65.9	Malignant neoplasm of unspecified renal pelvis	
C70.0	Malignant neoplasm of cerebral meninges	
C70.1	Malignant neoplasm of spinal meninges	
C70.9	Malignant neoplasm of meninges, unspecified	
C71.0	Malignant neoplasm of cerebrum, except lobes and ventricles	
C71.1	Malignant neoplasm of frontal lobe	
C71.2	Malignant neoplasm of temporal lobe	
C71.3	Malignant neoplasm of parietal lobe	
C71.4	Malignant neoplasm of occipital lobe	
C71.5	Malignant neoplasm of cerebral ventricle	
C71.6	Malignant neoplasm of cerebellum	
C71.7	Malignant neoplasm of brain stem	
C71.8	Malignant neoplasm of overlapping sites of brain	
C71.9	Malignant neoplasm of brain, unspecified	
C72.0	Malignant neoplasm of spinal cord	
C72.1	Malignant neoplasm of cauda equina	
C72.9	Malignant neoplasm of central nervous system, unspecified	
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	
C83.30	Diffuse large B-cell lymphoma unspecified site	
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites	
C83.80	Other non-follicular lymphoma unspecified site	
C83.89	Other non-follicular lymphoma extranodal and solid organ sites	
C85.89	Other specified types of non-Hodgkin lymphoma, extranodal and solid organ sites	
C85.99	Non-Hodgkin lymphoma, unspecified, extranodal and solid organ sites	
D19.1	Benign neoplasm of mesothelial tissue of peritoneum	
D32.0	Benign neoplasm of cerebral meninges	
D32.1	Benign neoplasm of spinal meninges	
D32.9	Benign neoplasm of meninges, unspecified	
D42.0	Neoplasm of uncertain behavior of cerebral meninges	
D42.1	Neoplasm of uncertain behavior of spinal meninges	
D42.9	Neoplasm of uncertain behavior of meninges, unspecified	

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ICD-10	ICD-10 Description	
D43.0	Neoplasm of uncertain behavior of brain, supratentorial	
D43.1	Neoplasm of uncertain behavior of brain, infratentorial	
D43.2	Neoplasm of uncertain behavior of brain, unspecified	
D43.4	Neoplasm of uncertain behavior of spinal cord	
D43.9	Neoplasm of uncertain behavior of central nervous system, unspecified	
D48.1	Neoplasm of uncertain behavior of connective and other soft tissue	
G93.6	Cerebral edema	
I67.89	Other cerebrovascular disease	
I67.9	Cerebrovascular disease, unspecified	
Y84.2	Radiological procedure and radiotherapy as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure	
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	
Z85.42	Personal history of malignant neoplasm of other parts of uterus	
Z85.43	Personal history of malignant neoplasm of ovary	
Z85.831	Personal history of malignant neoplasm of soft tissue	
Z85.841	Personal history of malignant neoplasm of brain	
Z85.848	Personal history of malignant neoplasm of other parts of nervous tissue	

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: <u>https://www.cms.gov/medicare-coverage-database/search.aspx</u>. Additional indications may be covered at the discretion of the health plan.

Medicare Part B Covered Diagnosis Codes (applicable to existing NCD/LCD/LCA):

 Jurisdiction(s): 6, K
 NCD/LCD Document (s): A52370

 https://www.cms.gov/medicare-coverage-database/new-search/searchresults.aspx?keyword=a52370&areaId=all&docType=NCA%2CCAL%2CNCD%2CMEDCAC%2CTA%2CMCD% 2C6%2C3%2C5%2C1%2CF%2CP

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	