



## Mvasi® (bevacizumab-awwb), Zirabev® (bevacizumab-bvcr)

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### Medical Guideline Disclaimer

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### Definition

Mvasi & Zirabev are recombinant humanized monoclonal IgG1 antibody that binds to vascular endothelial growth factor(VEGF) and inhibits the proliferation of endothelial cells and the formation of new blood vessels.

### Length of Authorization

Coverage will be provided for six months and may be renewed. For CNS cancers and recurrent glioblastoma (symptom management), coverage will be provided for 12 weeks and may NOT be renewed.

### Dosing Limits

#### Max Units (per dose and over time) [Medical Benefit]:

#### Oncology indications (J9035):

- 170 billable units per 21 days
- 120 billable units per 14 days

### Guideline

#### I. INITIAL APPROVAL CRITERIA

Mvasi and Zirabev are the preferred agents for Commercial, Medicaid, and Medicare members.

Coverage is provided in the following conditions:

- Patient must have no recent history of hemorrhage or hemoptysis (the presence 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**
- Patient must be 18 years of age or older

#### **Colorectal Cancer (CRC) <sup>1</sup>**

- Not used for adjuvant treatment; **AND**
- Patient's disease is metastatic; **AND**
  - Must be used as first- or second-line therapy in combination with a fluoropyrimidine- (e.g., 5-fluorouracil/5-FU or capecitabine) or irinotecan-based regimen; **OR**
  - Patient's disease has progressed on a first-line bevacizumab-containing regimen; **AND**
    - Used in combination with an irinotecan and/or oxaliplatin-based regimen (if not used first-line)

#### **Non-squamous non-small cell lung cancer (NSCLC) <sup>1</sup>**

- Patient's disease must be unresectable, locally advanced, or metastatic; **AND**
  - Used as first-line therapy in combination with either carboplatin and paclitaxel

#### **Recurrent Glioblastoma<sup>1</sup>**

- Used as treatment in adult patients

#### **Cervical Cancer <sup>1</sup>**

- Patient's disease must be persistent, recurrent, or metastatic; **AND**
- Used in combination with paclitaxel **AND** either cisplatin, carboplatin, or topotecan

#### **Breast cancer <sup>2</sup>**

- Patient must have recurrent or metastatic disease; **AND**
- Patient has a high tumor burden or rapidly progressive disease; **AND**
- Must be used in combination with paclitaxel; **AND**
- Patient must be human epidermal growth factor receptor 2 (HER2)-negative; **AND**
  - Disease is hormone receptor-negative; **OR**
  - Disease is hormone receptor-positive and refractory to endocrine therapy; **OR**
  - Patient has symptomatic visceral disease or visceral crisis

#### **Renal cell carcinoma (RCC) <sup>1</sup>**

- Patient must have metastatic or relapsed disease; **AND**
  - Must be used in combination with interferon-alfa <sup>1</sup>;

### **Central nervous system (CNS) cancer**

- Used for symptom management related to radiation necrosis, poorly controlled vasogenic edema or mass effect as single-agent short-course therapy; **AND**
  - Patient has a diagnosis of one of the following other CNS cancers:
    - Supratentorial Astrocytoma/Oligodendroglioma (Infiltrative, WHO Grade II); **OR**
    - Primary CNS Lymphoma; **OR**
    - Meningiomas; **OR**
    - Brain, Spine, or Leptomeningeal metastases; **OR**
    - Medulloblastoma; **OR**
    - Recurrent Glioblastoma<sup>1</sup> or Anaplastic Gliomas<sup>2</sup>; **OR**
    - Recurrent Intracranial or Spinal Ependymoma; **OR**
- Used as a single agent OR in combination with one of the following: irinotecan, carmustine, lomustine, or temozolomide in patients with recurrent Glioblastomas <sup>1</sup> or Anaplastic Gliomas <sup>2</sup>; **OR**
- Used as single agent therapy for patients with progressive disease who do not have subependymomas in patients with a diagnosis of recurrent Intracranial and Spinal Ependymoma <sup>2</sup>; **OR**
- Used for treatment of unresectable recurrent or progressive disease when radiation therapy is not an option in patients with a diagnosis of Meningiomas <sup>2</sup>

### **Soft tissue Sarcoma <sup>2</sup>**

- Used as a single agent for Angiosarcoma; **OR**
- Used in combination with temozolomide for Solitary Fibrous Tumor or Hemangiopericytoma

### **Endometrial Carcinoma <sup>2</sup>**

- Used as a single agent therapy for disease that has progressed on prior cytotoxic therapy; **OR**
- Used in combination with carboplatin and paclitaxel for advanced or recurrent disease

### **Malignant Pleural Mesothelioma <sup>2</sup>**

- Patient has unresectable or metastatic disease; **AND**
- Must be used in combination with pemetrexed and either cisplatin or carboplatin followed by single-agent maintenance therapy.

### **AIDS-Related Kaposi Sarcoma <sup>2</sup>**

- Patient has relapsed or refractory disease; **AND**
- Patient has advanced cutaneous, oral, visceral or nodal disease; **AND**
- Used as subsequent therapy in combination with antiretroviral therapy (ART) after failure to two lines of systemic therapy

<sup>1</sup> FDA-labeled indication(s); <sup>2</sup> Compendia recommended indication(s) <sup>23</sup> FDA-labeled Avastin only indication(s)

<b>Genomic Aberration Targeted Therapies (<i>not all inclusive</i>) §</b>
Sensitizing EGFR mutation-positive tumors <ul style="list-style-type: none"><li>– Erlotinib</li><li>– Afatinib</li><li>– Gefitinib</li><li>– Osimertinib</li></ul>
ALK rearrangement-positive tumors <ul style="list-style-type: none"><li>– Crizotinib</li><li>– Ceritinib</li><li>– Brigatinib</li><li>– Alectinib</li></ul>
ROS1 rearrangement-positive tumors <ul style="list-style-type: none"><li>– Crizotinib</li><li>– Ceritinib</li></ul>
BRAF V600E-mutation positive tumors <ul style="list-style-type: none"><li>– Dabrafenib/Trametinib</li></ul>
PD-L1 expression-positive tumors (>50%) <ul style="list-style-type: none"><li>– Pembrolizumab</li></ul>

## II. RENEWAL CRITERIA

Coverage can be renewed based upon the following criteria:

- Patient continues to meet criteria identified above; **AND**
- Tumor response with 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 perforation, surgical/wound healing complications, hemorrhage, arterial and venous thromboembolic events (ATE & VTE), uncontrolled hypertension, posterior reversible encephalopathy syndrome (PRES), nephrotic syndrome, severe infusion reactions, ovarian failure, congestive heart failure (CHF), etc.; **AND**

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

May NOT be renewed **Metastatic carcinoma of the colon or rectum (additional renewal opportunity):**

- Patient’s disease has progressed on a first-line bevacizumab-containing regimen; **AND**
  - Used in combination with an irinotecan and/or oxaliplatin-based regimen (if not used first line)

**Malignant Pleural Mesothelioma – maintenance therapy:**

- Must be used as a single agent

**Non-squamous non-small cell lung cancer – continuation maintenance therapy:**

- Mvasi must have been included in patient’s 1<sup>st</sup> line chemotherapy

### Dosing/Administration

Indication	Dose
Metastatic Colorectal Cancer	5 mg/kg every 2 weeks in combination with bolus-IFL 10 mg/kg every 2 weeks in combination with FOLFOX4 5 mg/kg every 2 weeks or 7.5 mg/kg every 3 weeks in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy in patients who have progressed on a first-line bevacizumab product-containing regimen
Cervical Cancer	15mg/kg every three weeks until disease progression or unacceptable toxicity
First-line NSCLC	15 mg/kg every 3 weeks in combination with carboplatin and paclitaxel
CNS Cancers	–For disease treatment: 10 mg/kg every 2 weeks until disease progression or unacceptable toxicity. –For symptom management: 5-10 mg/kg every 2 weeks up to 12 weeks duration
Recurrent Glioblastoma	10 mg/kg every 2 weeks
Metastatic Renal Cell Carcinoma	10 mg/kg every 2 weeks in combination with interferon-alfa
Persistent, Recurrent or Metastatic Cervical Cancer	15 mg/kg every 3 weeks in combination with paclitaxel and cisplatin, or in combination with paclitaxel and topotecan
MPM	15 mg/kg every 3 weeks in combination with chemotherapy for up to 6 cycles followed by single agent use, at the same dose/frequency, until disease progression or unacceptable toxicity.
All Other Oncology Indications	5-10 mg/kg every 2 weeks <b>OR</b> 7.5-15 mg/kg every 3 weeks

### Authorization

### Applicable Procedure Codes

Q5107	Injection, bevacizumab-awwb, biosimilar, (Mvasi) 10 mg
Q5118	Injection, bevacizumab-bvcr, biosimilar, (Zirabev), 10 mg, effective 10/01/2019

### Applicable NDC's

55513-0206-01	Mvasi single-use vial, 100 mg/4ml solution for injection
55513-0207-01	Mvasi single-use vial, 400 mg/16 mL solution for injection
00069-0315-01	ZIRABEV (bevacizumab-bvzr) injection single dose vial 100 mg/4 mL (25 mg/mL)
00069-0342-01	ZIRABEV (bevacizumab-bvzr) injection single dose vial 400 mg/16 mL (25 mg/mL)

ICD-10	ICD-10 Description
C17.0	Malignant neoplasm duodenum
C17.1	Malignant neoplasm jejunum
C17.2	Malignant neoplasm ileum
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
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 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
C38.4	Malignant neoplasm of pleura
C45.0	Mesothelioma of pleura
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
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
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
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
C50.011	Malignant neoplasm of nipple and areola, right female breast
C50.012	Malignant neoplasm of nipple and areola, left female breast
C50.019	Malignant neoplasm of nipple and areola, unspecified female breast
C50.021	Malignant neoplasm of nipple and areola, right male breast
C50.022	Malignant neoplasm of nipple and areola, left male breast
C50.029	Malignant neoplasm of nipple and areola , unspecified male breast
C50.111	Malignant neoplasm of central portion of right female breast
C50.112	Malignant neoplasm of central portion of left female breast
C50.119	Malignant neoplasm of central portion of unspecified female breast
C50.121	Malignant neoplasm of central portion of right male breast
C50.122	Malignant neoplasm of central portion of left male breast
C50.129	Malignant neoplasm of central portion of unspecified male breast
C50.211	Malignant neoplasm of upper-inner quadrant of right female breast
C50.212	Malignant neoplasm of upper-inner quadrant of left female breast
C50.219	Malignant neoplasm of upper-inner quadrant of unspecified female breast
C50.221	Malignant neoplasm of upper-inner quadrant of right male breast
C50.222	Malignant neoplasm of upper-inner quadrant of left male breast
C50.229	Malignant neoplasm of upper-inner quadrant of unspecified male breast
C50.311	Malignant neoplasm of lower-inner quadrant of right female breast
C50.312	Malignant neoplasm of lower-inner quadrant of left female breast
C50.319	Malignant neoplasm of lower-inner quadrant of unspecified female breast
C50.321	Malignant neoplasm of lower-inner quadrant of right male breast
C50.322	Malignant neoplasm of lower-inner quadrant of left male breast
C50.329	Malignant neoplasm of lower-inner quadrant of unspecified male breast
C50.411	Malignant neoplasm of upper-outer quadrant of right female breast
C50.412	Malignant neoplasm of upper-outer quadrant of left female breast
C50.419	Malignant neoplasm of upper-outer quadrant of unspecified female breast
C50.421	Malignant neoplasm of upper-outer quadrant of right male breast
C50.422	Malignant neoplasm of upper-outer quadrant of left male breast
C50.429	Malignant neoplasm of upper-outer quadrant of unspecified male breast
C50.511	Malignant neoplasm of lower-outer quadrant of right female breast
C50.512	Malignant neoplasm of lower-outer quadrant of left female breast
C50.519	Malignant neoplasm of lower-outer quadrant of unspecified female breast



C50.521	Malignant neoplasm of lower-outer quadrant of right male breast
C50.522	Malignant neoplasm of lower-outer quadrant of left male breast
C50.529	Malignant neoplasm of lower-outer quadrant of unspecified male breast
C50.611	Malignant neoplasm of axillary tail of right female breast
C50.612	Malignant neoplasm of axillary tail of left female breast
C50.619	Malignant neoplasm of axillary tail of unspecified female breast
C50.621	Malignant neoplasm of axillary tail of right male breast
C50.622	Malignant neoplasm of axillary tail of left male breast
C50.629	Malignant neoplasm of axillary tail of unspecified male breast
C50.811	Malignant neoplasm of overlapping sites of right female breast
C50.812	Malignant neoplasm of overlapping sites of left female breast
C50.819	Malignant neoplasm of overlapping sites of unspecified female breast
C50.821	Malignant neoplasm of overlapping sites of right male breast
C50.822	Malignant neoplasm of overlapping sites of left male breast
C50.829	Malignant neoplasm of overlapping sites of unspecified male breast
C50.911	Malignant neoplasm of unspecified site of right female breast
C50.912	Malignant neoplasm of unspecified site of left female breast
C50.919	Malignant neoplasm of unspecified site of unspecified female breast
C50.921	Malignant neoplasm of unspecified site of right male breast
C50.922	Malignant neoplasm of unspecified site of left male breast
C50.929	Malignant neoplasm of unspecified site of unspecified male breast
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
C56.9	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
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
C72.9	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
C79.32	Secondary malignant neoplasm of cerebral meninges
C79.89	Secondary malignant neoplasm of other specified sites
C79.9	Secondary malignant neoplasm of unspecified site
C83.30	Diffuse large B-cell lymphoma unspecified site
C83.31	Diffuse large B-cell lymphoma lymph nodes of head, face, and neck
C83.39	Diffuse large B-cell lymphoma extranodal and solid organ sites
C83.80	Other non-follicular lymphoma unspecified site
C83.81	Other non-follicular lymphoma lymph nodes of head, face, and neck
C83.89	Other non-follicular lymphoma extranodal and solid organ sites
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
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
I67.89	Other cerebrovascular disease
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
Z85.3	Personal history of malignant neoplasm of breast
Z85.43	Personal history of malignant neoplasm of ovary
Z80.49	Family history of malignant neoplasm of other genital organs
Z85.528	Personal history of other malignant neoplasm of kidney
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

## Revision History

03/31/2020	Added under Initial Criteria: <b>Effective Date: 07/01/2020</b> , Mvasi and Zirabev are the preferred agents for Commercial and Medicaid members. Member must fail trial of Mvasi AND Zirabev, prior to using Avastin (Only Commercial and Medicaid members are subject to this step therapy).
10/24/2019	Added under criteria: Patient must be 18 years of age or older -Under length of authorization, added recurrent glioblastoma, for coverage 12 weeks and may NOT be renewed. -Under non-squamous non-small cell lung cancer, removed disease must be recurrent in the criteria, updated used as first-line therapy in combination with carboplatin and paclitaxel. -Added Recurrent Glioblastoma – and used as treatment in adult patients -Under Metastatic Colorectal Cancer, updated dosing to package insert -Added under dosing for Recurrent Glioblastoma 10mg/kg every 2 weeks -Added under dosing for Persistent, Recurrent or Metastatic Cervical Cancer 15mg/kg every three weeks in combination with paclitaxel and cisplatin, or in combination with paclitaxel and topotecan
09/23/2019	Added Zirabev Q5118, effective 10/01/2019.

## References

1. Mvasi [package insert]. Thousand Oaks, CA, Amgen, 2017.
2. Clinical Pharmacology Elsevier Gold Standard. 2018.
3. Micromedex Healthcare Series: Thomson Micromedex, Greenwood Village, Co 2018.
4. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium.2018.
5. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs.. Bethesda, MD. 2018.
6. Product Information: ZIRABEV(TM) intravenous injection, bevacizumab-bvzr intravenous injection. Pfizer Labs (per FDA), New York, NY, 2019.