Resource Guide

MVASI® is a biosimilar to Avastin® (bevacizumab), backed by Amgen expertise[1]

MVASI®
(bevacizumab-awwb)
Injection 100mg/vial & 400mg/vial

INDICATIONS

MVASI® is a vascular endothelial growth factor inhibitor indicated for the treatment of:

MVASI™, in combination with intravenous fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer (mCRC).

MVASI®, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with mCRC who have progressed on a first-line bevacizumab product-containing regimen.

Limitations of Use: MVASI® is not indicated for adjuvant treatment of colon cancer.

MVASI®, in combination with carboplatin and paclitaxel, is indicated for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC).

MVASI® is indicated for the treatment of recurrent glioblastoma (GBM) in adults.

MVASI®, in combination with interferon-alfa, is indicated for the treatment of metastatic renal cell carcinoma (mRCC).

MVASI®, in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer (CC).

MVASI®, in combination with carboplatin and paclitaxel, followed by MVASI as a single agent, is indicated for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection (OC).

MVASI®, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, is indicated for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens (OC).

MVASI®, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by MVASI as a single agent, is indicated for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (OC).

Please see full Important Safety Information and click here for full Prescribing Information.

This brochure does not take the place of the reconstitution and preparation instructions located in the full Prescribing Information (PI). Please refer to the PI for specific instructions on preparing MVASI®.

AMGEN

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Amgen can provide conversion support for institutions, including staff training, reimbursement assistance, and to facilitate an easier transition to MVASI®.



IMPORTANT SAFETY INFORMATION

Serious adverse reactions (Warnings and Precautions)

- Serious and sometimes fatal adverse reactions with increased incidence in the bevacizumab-treated arm vs chemotherapy arm included:
  - Gastrointestinal (GI) perforation ranged from 0.3% to 3% of patients across clinical studies
  - Non-GI fistulae (<1% to 1.8%, highest in patients with cervical cancer)
  - Arterial thromboembolic events (Grade ≥3, 5%, highest in patients with GBM)
  - The incidence of wound healing and surgical complications, including serious and fatal complications, is increased in MVASI®-treated patients

MVASI®
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Injection 100mg/vial & 400mg/vial

Please see full Important Safety Information and click here for full Prescribing Information.

SUPPLY AND STORAGE

SUPPLY[1]

MVASI® is supplied as a sterile, colorless to pale yellow, preservative-free solution containing 25 mg/mL of bevacizumab-awwb in a single-dose vial. The vial stopper contains dry natural rubber.

Each carton of MVASI® contains either:

- 100 mg of MVASI® in 4 mL (25 mg/mL)
  NDC numbers are: 55513-0206-01, 55513-0206-21[1]
- 400 mg of MVASI® in 16 mL (25 mg/mL)
  NDC numbers are: 55513-0207-01, 55513-0207-21[1]

STORAGE[1]



- Store at 2° to 8°C (36° to 46°F) in the original carton until time of use. MVASI® vials should be protected from light.
- Diluted MVASI® solution may be stored at 2°C to 8°C (36°F to 46°F) for up to 8 hours, if not used immediately.



DO NOT FREEZE OR SHAKE.
Discard any unused portion remaining in the vial.

IMPORTANT SAFETY INFORMATION (cont'd)
Serious adverse reactions (Warnings and Precautions)

- Serious and sometimes fatal adverse reactions with increased incidence in the bevacizumab-treated arm vs chemotherapy arm included:
  - Hemorrhage (Grade 3–5) ranged from 0.4% to 7% of patients across clinical studies
  - Renal injury and proteinuria
    - Grade 3–4 proteinuria ranged from 0.7% to 7% in clinical studies
    - Nephrotic syndrome (<1%)

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MVASI®
(bevacizumab-awwb)
Injection 100mg/vial & 400mg/vial

PREPARATION AND ADMINISTRATION

DILUTION[1]

Use appropriate aseptic technique. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.



- MVASI® is a colorless to pale yellow solution. Do not use vial if solution is cloudy, discolored, or contains particulate matter.



- Withdraw necessary amount of MVASI® and dilute in a total volume of 100 mL of 0.9% Sodium Chloride Injection, USP. Discard any unused portion left in a vial, as the product contains no preservatives.



- Do not administer or mix with dextrose solution.

ADMINISTRATION[1]

Administer only as an intravenous (IV) infusion. Do not administer as an intravenous push or bolus.

- Do not initiate MVASI® until at least 28 days following major surgery. Administer MVASI® after the surgical incision has fully healed.
- First infusion: Administer over 90 minutes.
- Subsequent infusions: Administer over 60 minutes if first infusion is tolerated; administer all subsequent infusions over 30 minutes if infusion over 60 minutes is tolerated.

IMPORTANT SAFETY INFORMATION (cont'd)

- Additional serious adverse reactions with increased incidence in the bevacizumab-treated arm vs chemotherapy arm included:
  - Venous thromboembolism (Grade ≥3, 11% seen in GOG-0240)
  - Hypertension (Grade 3–4, 5%–18%)
  - Posterior reversible encephalopathy syndrome (PRES) (<0.5%)

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MVASI® (bevacizumab-awwb) Injection 100mg/vial & 400mg/vial

RECOMMENDED DOSES AND SCHEDULES

METASTATIC COLORECTAL CANCER (mCRC)[1]				
WITH IFL CHEMOTHERAPY	Every 2 Weeks 5 mg/kg			
WITH FOLFOX4	Every 2 Weeks 10 mg/kg			
WITH BEVACIZUMAB-AWWB + FLUOROPYRIMIDINE AND IRINOTECAN OR OXALIPLATIN	Every 2 Weeks 5 mg/kg	OR	Every 3 Weeks 7.5 mg/kg	
NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC)[1]				
WITH CARBOPLATIN + PACLITAXEL	Every 3 Weeks 15 mg/kg			
RECURRENT GLIOBLASTOMA (rGBM)[1]				
AS SINGLE AGENT	Every 2 Weeks 10 mg/kg			
METASTATIC RENAL CELL CARCINOMA (mRCC)[1]				
WITH INTERFERON ALFA	Every 2 Weeks 10 mg/kg			
CERVICAL CANCER (CC)[1]				
WITH PACLITAXEL + CISPLATIN OR PACLITAXEL + TOPOTECAN	Every 3 Weeks 15 mg/kg			

IFL = irinotecan, leucovorin (folinic acid), and fluorouracil; FOLFOX4 = fluorouracil, leucovorin, and oxaliplatin.

- Patients should continue treatment until disease progression or unacceptable toxicity.[1]

IMPORTANT SAFETY INFORMATION (cont'd)

- Additional serious adverse reactions with increased incidence in the bevacizumab-treated arm vs chemotherapy arm included:
  - Congestive heart failure (CHF): Grade ≥3 left ventricular dysfunction (1%)
- Infusion-related reactions, including but not limited to anaphylactoid/anaphylactic reactions, have occurred. In clinical studies, infusion-related reactions with the first dose of bevacizumab occurred in <3% of patients, and severe reactions occurred in 0.4% of patients

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MVASI® (bevacizumab-awwb) Injection 100mg/vial & 400mg/vial

CODING

NATIONAL DRUG CODES (NDCs)[1]

BILLING	Each single-dose carton contains one vial of MVASI® (100 mg of bevacizumab-awwb) in 4 mL (25 mg/mL): NDC numbers are: 55513-0206-01, 55513-0206-21[1]
	Each single-dose carton contains one vial of MVASI® (400 mg of bevacizumab-awwb) in 16 mL (25 mg/mL): NDC numbers are: 55513-0207-01, 55513-0207-21[1]

METASTATIC COLORECTAL CANCER (mCRC)

ICD-10-CM[2]	Malignant neoplasm of the following:	
	Cecum	C18.0-C18.1
	Colon (various sites)	C18.2-C18.9
	Rectosigmoid junction	C19
	Rectum, rectal ampulla	C20
	Overlapping sites of rectum, anus, and anal canal	C21.8
HCPCS[3]	Q5107 injection, bevacizumab-awwb, 10 mg	
CPT®[4]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure.	

ICD = international classification of diseases; HCPCS = healthcare common procedure coding system; CPT = current procedural terminology.

IMPORTANT SAFETY INFORMATION (cont'd)

- Avoid use in patients with ovarian cancer who have evidence of recto-sigmoid involvement by pelvic examination or bowel involvement on CT scan or clinical symptoms of bowel obstruction
- Inform females of reproductive potential of the risk of ovarian failure prior to initiating treatment with MVASI®

Pregnancy warning

- Based on the mechanism of action and animal studies, MVASI® may cause fetal harm
- Advise female patients that MVASI® may cause fetal harm, and to inform their healthcare provider of a known or suspected pregnancy

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CODING (cont'd)

NON-SQUAMOUS NON-SMALL CELL LUNG CANCER (NSCLC)

ICD-10-CM[2]	Malignant neoplasm of the following:	
	Trachea	C33
	Bronchus and lung, main bronchus	C34.00-C34.02
	Upper lobe, bronchus or lung	C34.10-C34.12
	Middle lobe, bronchus or lung	C34.2
	Lower lobe, bronchus or lung	C34.30-C34.32
	Overlapping sites, bronchus or lung	C34.80-C34.82
	Unspecified part, bronchus or lung	C34.90-C34.92
HCPCS[3]	Q5107 injection, bevacizumab-awwb, 10 mg	
CPT®[4]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure.	

GLIOBLASTOMA

ICD-10-CM[2]	Malignant neoplasm of the brain	C71.0-71.9
HCPCS[3]	Q5107 injection, bevacizumab-awwb, 10 mg	
CPT®[4]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure.	

IMPORTANT SAFETY INFORMATION (cont'd)

- Advise females of reproductive potential to use effective contraception during treatment with MVASI® and for 6 months after the last dose of MVASI®
- Advise nursing women not to breastfeed during treatment with MVASI® and for 6 months following their last dose of treatment
- MVASI® may impair fertility

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CODING (cont'd)

METASTATIC RENAL CELL CARCINOMA (mRCC)

ICD-10-CM[2]	Malignant neoplasm of the following:	
	Right and left kidney, except renal pelvis	C64.1-C64.2
	Unspecified kidney, except renal pelvis	C64.9
	Renal pelvis	C65.1-C65.2, C65.9
HCPCS[3]	Q5107 injection, bevacizumab-awwb, 10 mg	
CPT®[4]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure.	

PERSISTENT, RECURRENT, OR METASTATIC CARCINOMA OF THE CERVIX

ICD-10-CM[2]	Malignant neoplasm of the following:	
	Endocervix and exocervix	C53.0-C53.1
	Overlapping sites of cervix uteri and unspecified sites of the cervix uteri	C53.8-C53.9
HCPCS[3]	Q5107 injection, bevacizumab-awwb, 10 mg	
CPT®[4]	**96413:** Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	96415: Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	96417: Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to one hour. Must be listed separately in addition to code for primary procedure.	

IMPORTANT SAFETY INFORMATION (cont'd)

Most common adverse reactions

- Across studies, the most common adverse reactions observed in bevacizumab patients at a rate >10% were:
  - Epistaxis
  - Headache
  - Hypertension
  - Rhinitis
  - Proteinuria
  - Taste alteration
  - Dry skin
  - Hemorrhage
  - Lacrimation disorder
  - Back pain
  - Exfoliative dermatitis
- Across all studies, bevacizumab was discontinued in 8% to 22% of patients because of adverse reactions

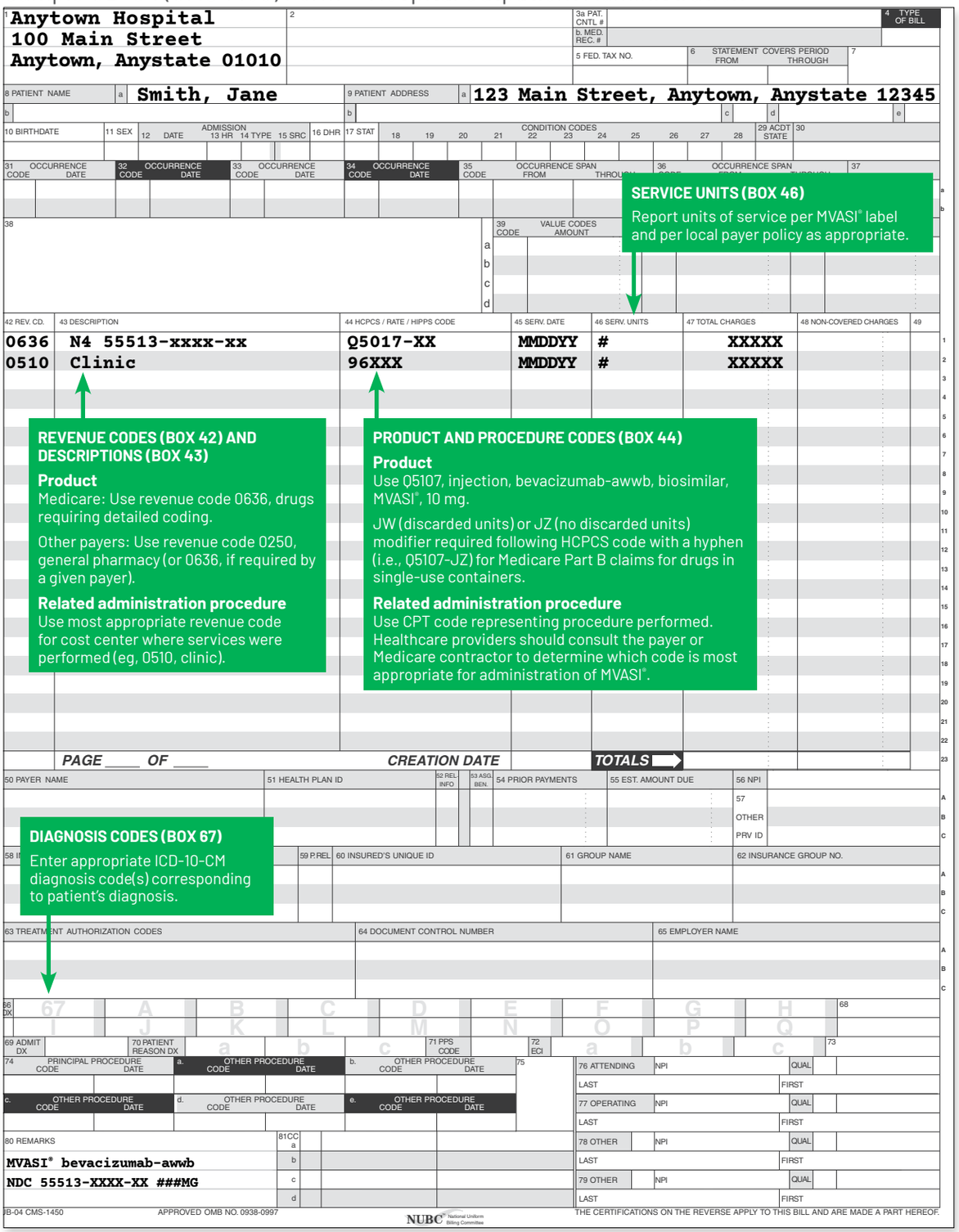
Please see full Important Safety Information and click here for full Prescribing Information.

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HOSPITAL CODING FORM

The CMS 1450 for Hospital Outpatient

Sample UB-04 (CMS 1450) Form — Hospital Outpatient Administration



SERVICE UNITS (BOX 46)

Report units of service per MVASI® label and per local payer policy as appropriate.

REVENUE CODES (BOX 42) AND DESCRIPTIONS (BOX 43)

Product

Medicare: Use revenue code 0636, drugs requiring detailed coding.

Other payers: Use revenue code 0250, general pharmacy (or 0636, if required by a given payer).

Related administration procedure

Use most appropriate revenue code for cost center where services were performed (eg, 0510, clinic).

PRODUCT AND PROCEDURE CODES (BOX 44)

Product

Use Q5107, injection, bevacizumab-awwb, biosimilar, MVASI®, 10 mg.

JW (discarded units) or JZ (no discarded units) modifier required following HCPCS code with a hyphen (i.e., Q5107-JZ) for Medicare Part B claims for drugs in single-use containers.

Related administration procedure

Use CPT code representing procedure performed. Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of MVASI®.

DIAGNOSIS CODES (BOX 67)

Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis.

This sample form is intended as a reference for coding and billing for product and associated services. It is not intended to be directive; the use of the recommended codes does not guarantee reimbursement. Healthcare providers may deem other codes or policies more appropriate and should select the coding options that most accurately reflect their internal system guidelines, payer requirements, practice patterns, and the services rendered. Healthcare providers are responsible for ensuring the accuracy and validity of all billing and claims for appropriate reimbursement.

Coding Information

JW/JZ Modifiers:
Effective for dates of service on or after July 1, 2023, Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.

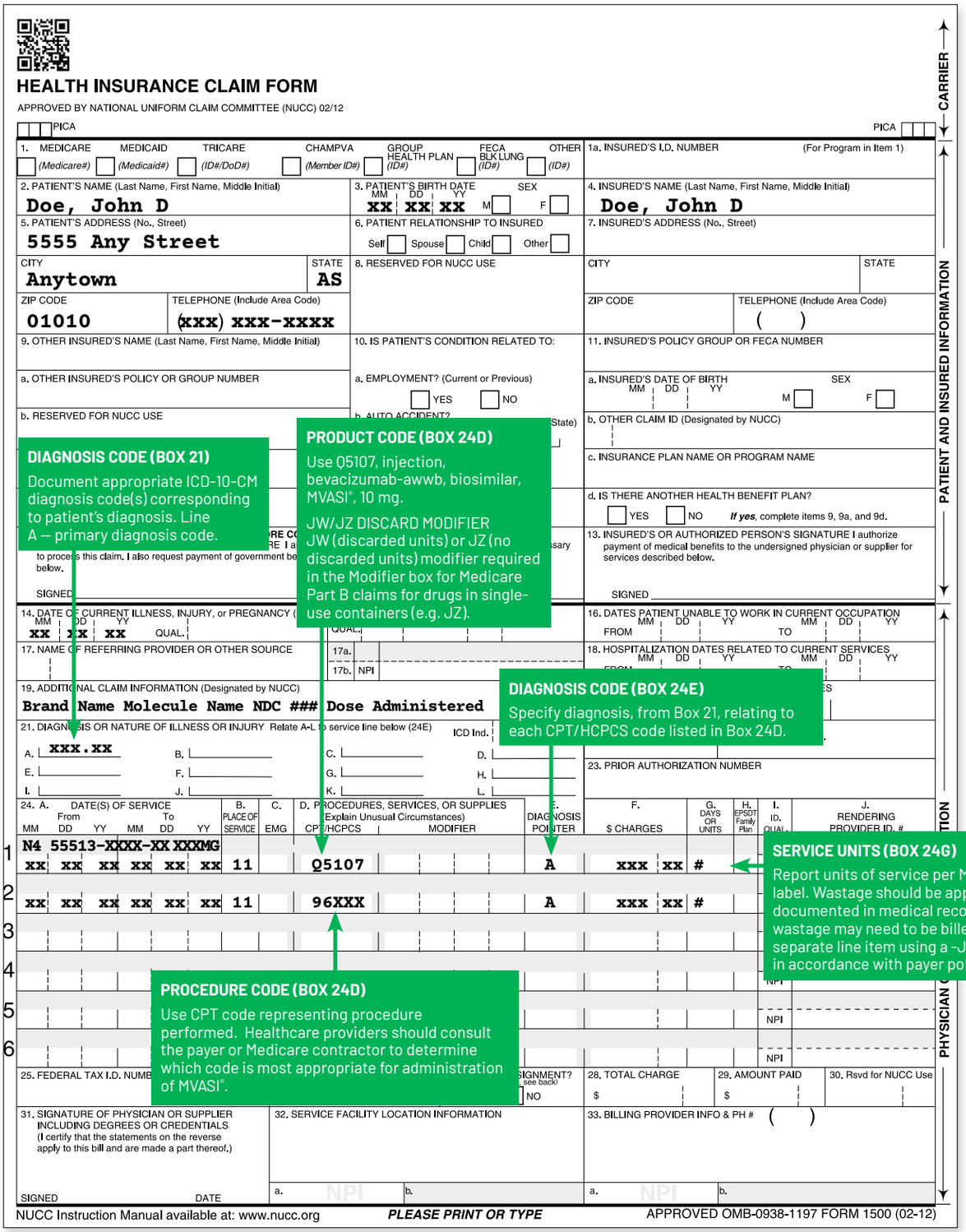
JG/TB Modifiers:
Beginning January 1, 2023, Medicare requires that all claims submitted by 340B covered entities on OPPS claims (bill type 13X) for separately payable Part B drugs and biologicals must include modifiers "JG" (drug or biological acquired with 340B drug pricing program discount, reported for informational purposes) or "TB" (drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities) on claim lines for drugs acquired through the 340B Drug Discount Program. While covered entities may use "JG" or "TB" modifier for claims with dates of service through December 31, 2024, beginning January 1, 2025, all covered entities must transition to the "TB" modifier.

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PHYSICIAN CODING FORM

The CMS 1500 for Physician Office

Sample CMS 1500 Form — Physician Office Administration



DIAGNOSIS CODE (BOX 21)
Document appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis. Line A — primary diagnosis code.

PRODUCT CODE (BOX 24D)
Use Q5107, injection, bevacizumab-awwb, biosimilar, MVASI®, 10 mg.

JW/JZ DISCARD MODIFIER
JW (discarded units) or JZ (no discarded units) modifier required in the Modifier box for Medicare Part B claims for drugs in single-use containers (e.g. JZ).

DIAGNOSIS CODE (BOX 24E)
Specify diagnosis, from Box 21, relating to each CPT/HCPCS code listed in Box 24D.

SERVICE UNITS (BOX 24G)
Report units of service per MVASI® label. Wastage should be appropriately documented in medical records; wastage may need to be billed on a separate line item using a -JW modifier in accordance with payer policy.

PROCEDURE CODE (BOX 24D)
Use CPT code representing procedure performed. Healthcare providers should consult the payer or Medicare contractor to determine which code is most appropriate for administration of MVASI®.

Coding Information
JW/JZ Modifiers:
Effective for dates of service on or after July 1, 2023. Medicare Part B claims require the use of the new JZ modifier for single-use vials and containers when there are no discarded drug amounts. Medicare claims also continue to require the use of the JW modifier (drug amount discarded/not administered to any patient) for drugs and biologicals that are separately payable under Medicare Part B with discarded amounts from single-dose containers.

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MVASI® (bevacizumab-awwb) Injection 100mg/vial & 400mg/vial

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MVASI® PRODUCT FACT SHEET

INDICATIONS

MVASI® is a vascular endothelial growth factor inhibitor indicated for the treatment of:

MVASI®, in combination with intravenous fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer (mCRC).

MVASI®, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with mCRC who have progressed on a first-line bevacizumab product-containing regimen.

Limitations of Use: MVASI® is not indicated for adjuvant treatment of colon cancer.

MVASI®, in combination with carboplatin and paclitaxel, is indicated for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC).

MVASI® is indicated for the treatment of recurrent glioblastoma (GBM) in adults.

MVASI®, in combination with interferon-alfa, is indicated for the treatment of metastatic renal cell carcinoma (mRCC).

MVASI®, in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer (CC).

MVASI®, in combination with carboplatin and paclitaxel, followed by MVASI as a single agent, is indicated for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection (OC).

MVASI®, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, is indicated for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens (OC).

MVASI®, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by MVASI as a single agent, is indicated for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (OC).

PRODUCT INFORMATION

NDC	Description	Quantity
55513-0206-01, 55513-0206-21	100 mg of MVASI® in 4 mL (25 mg/mL)	One per carton
55513-0207-01, 55513-0207-21	400 mg of MVASI® in 16 mL (25 mg/mL)	One per carton

STORAGE AND HANDLING REQUIREMENTS

Store at 2° to 8°C (36° to 46°F) in the original carton until time of use. MVASI® vials should be protected from light. DO NOT FREEZE OR SHAKE. Discard any unused portion remaining in the vial. Diluted MVASI® solution may be stored at 2°C to 8°C (36°F to 46°F) for up to 8 hours, if not used immediately. Store undiluted vials at 2° to 8°C (36° to 46°F) in the original carton until time of use. MVASI® vials should be protected from light.

SHIPPING CONTAINER INFORMATION

MVASI® should be unpacked and refrigerated.

MVASI® should not be stored in the shipping container.

PRODUCT EXPIRATION

The expiration date is printed on each dispensing pack and vial label.

SUPPLIED AND MARKETED BY

Amgen USA Inc.
amgen.com
MVASI.com

PRODUCT RETURNS

For information and instructions regarding product returns, please contact your wholesaler or Amgen Trade Operations at 1-800-28-AMGEN (1-800-282-6436). Credit for returns is subject to Amgen's current Product Return Policy.

PRODUCT INFORMATION

Medical Information: 1-800-77-AMGEN (1-800-772-6436)

REIMBURSEMENT INFORMATION

Amgen SupportPlus: 866-264-2778 or www.AmgenSupportPlus.com

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IMPORTANT SAFETY INFORMATION

Serious adverse reactions (Warnings and Precautions)

- Serious and sometimes fatal adverse reactions with increased incidence in the bevacizumab-treated arm vs chemotherapy arm included:
  - Gastrointestinal (GI) perforation ranged from 0.3% to 3% of patients across clinical studies
  - Non-GI fistulae (<1% to 1.8%, highest in patients with cervical cancer)
  - Arterial thromboembolic events (Grade ≥3, 5%, highest in patients with GBM)
  - The incidence of wound healing and surgical complications, including serious and fatal complications, is increased in MVASI®-treated patients
  - Hemorrhage (Grade 3–5) ranged from 0.4% to 7% of patients across clinical studies
  - Renal injury and proteinuria
    - Grade 3–4 proteinuria ranged from 0.7% to 7% in clinical studies
    - Nephrotic syndrome (<1%)
- Additional serious adverse reactions with increased incidence in the bevacizumab-treated arm vs chemotherapy arm included:
  - Venous thromboembolism (Grade ≥3, 11% seen in GOG-0240)
  - Hypertension (Grade 3–4, 5%–18%)
  - Posterior reversible encephalopathy syndrome (PRES) (<0.5%)
  - Congestive heart failure (CHF): Grade ≥3 left ventricular dysfunction (1%)
- Infusion-related reactions, including but not limited to anaphylactoid/anaphylactic reactions, have occurred. In clinical studies, infusion-related reactions with the first dose of bevacizumab occurred in <3% of patients, and severe reactions occurred in 0.4% of patients
- Avoid use in patients with ovarian cancer who have evidence of recto-sigmoid involvement by pelvic examination or bowel involvement on CT scan or clinical symptoms of bowel obstruction
- Inform females of reproductive potential of the risk of ovarian failure prior to initiating treatment with MVASI®

Pregnancy warning

- Based on the mechanism of action and animal studies, MVASI® may cause fetal harm
- Advise female patients that MVASI® may cause fetal harm, and to inform their healthcare provider of a known or suspected pregnancy
- Advise females of reproductive potential to use effective contraception during treatment with MVASI® and for 6 months after the last dose of MVASI®
- Advise nursing women not to breastfeed during treatment with MVASI® and for 6 months following their last dose of treatment
- MVASI® may impair fertility

Most common adverse reactions

- Across studies, the most common adverse reactions observed in bevacizumab patients at a rate >10% were:
  - Epistaxis
  - Headache
  - Hypertension
  - Rhinitis
  - Proteinuria
  - Taste alteration
  - Dry skin
  - Hemorrhage
  - Lacrimation disorder
  - Back pain
  - Exfoliative dermatitis
- Across all studies, bevacizumab was discontinued in 8% to 22% of patients because of adverse reactions

Indication-specific adverse reactions

- In CC, Grade 3 or 4 adverse reactions in Study GOG-0240, occurring at a higher incidence (≥2%) in 218 patients receiving bevacizumab plus chemotherapy compared to 222 patients receiving chemotherapy alone, were abdominal pain (12% vs 10%), diarrhea (6% vs 3%), anal fistula (4% vs 0%), proctalgia (3% vs 0%), urinary tract infection (8% vs 6%), cellulitis (3% vs 0.5%), fatigue (14% vs 10%), hypertension (11% vs 0.5%), thrombosis (8% vs 3%), hypokalemia (7% vs 4%), hyponatremia (4% vs 1%), dehydration (4% vs 0.5%), neutropenia (8% vs 4%), lymphopenia (6% vs 3%), back pain (6% vs 3%), and pelvic pain (6% vs 1%)
- In mRCC, the most common Grade 3–5 adverse reactions in AVOREN, occurring at a >2% higher incidence in bevacizumab-treated patients vs controls, were fatigue (13% vs 8%), asthenia (10% vs 7%), proteinuria (7% vs 0%), hypertension (6% vs 1%, including hypertension and hypertensive crisis), and hemorrhage (3% vs 0.3%; including epistaxis, small intestinal hemorrhage, aneurysm ruptured, gastric ulcer hemorrhage, gingival bleeding, hemoptysis, hemorrhage intracranial, large intestinal hemorrhage, respiratory tract hemorrhage, and traumatic hematoma)
- In rGBM Study EORTC 26101, the incidence of Grade 3–4 VTE was 5% in patients receiving bevacizumab with chemotherapy compared to 2% in patients receiving chemotherapy alone. In this study, 22% of patients discontinued treatment in the bevacizumab with lomustine arm due to adverse reactions compared with 10% of patients in the lomustine arm. In patients receiving bevacizumab with lomustine, the adverse reaction profile was similar to that observed in other approved indications
- In NSCLC, Grade 3–5 (nonhematologic) and Grade 4–5 (hematologic) adverse reactions in Study E4599 occurring at a ≥2% higher incidence in bevacizumab-treated patients vs controls were neutropenia (27% vs 17%), fatigue (16% vs 13%), hypertension (8% vs 0.7%), infection without neutropenia (7% vs 3%), venous thromboembolism (5% vs 3%), febrile neutropenia (5% vs 2%), pneumonitis/pulmonary infiltrates (5% vs 3%), infection with Grade 3 or 4 neutropenia (4% vs 2%), hyponatremia (4% vs 1%), headache (3% vs 1%), and proteinuria (3% vs 0%)
- In first-line mCRC, the most common Grade 3–4 reactions in Study 2107, which occurred at a ≥2% higher incidence in the bevacizumab plus IFL vs IFL groups, were asthenia (10% vs 7%), abdominal pain (8% vs 5%), pain (8% vs 5%), hypertension (12% vs 2%), deep vein thrombosis (9% vs 5%), intra-abdominal thrombosis (3% vs 1%), syncope (3% vs 1%), diarrhea (34% vs 25%), constipation (4% vs 2%), leukopenia (37% vs 31%), and neutropenia (21% vs 14%)

IMPORTANT SAFETY INFORMATION (cont'd)

- In second-line mCRC, the most common Grade 3–5 (nonhematologic) and 4–5 (hematologic) reactions in Study E3200, which occurred at a higher incidence (≥2%) in the bevacizumab plus FOLFOX4 vs FOLFOX4 groups, were fatigue (19% vs 13%), diarrhea (18% vs 13%), sensory neuropathy (17% vs 9%), nausea (12% vs 5%), vomiting (11% vs 4%), dehydration (10% vs 5%), hypertension (9% vs 2%), abdominal pain (8% vs 5%), hemorrhage (5% vs 1%), other neurological (5% vs 3%), ileus (4% vs 1%), and headache (3% vs 0%). These data are likely to underestimate the true adverse event rates due to the reporting mechanisms used in this study
- When continued beyond first progression in mCRC, no new safety signals were observed in the TML study (ML18147) when bevacizumab was administered in second-line mCRC patients who progressed on a bevacizumab containing regimen in first-line mCRC. The safety data was consistent with the known safety profile established in first- and second-line mCRC
- In Stage III or IV OC after primary surgery, 608 patients received CP+Avastin→Avastin, 607 patients received CP+Avastin→PBO, and 602 patients received CP+PBO→PBO. Grade 3–4 adverse reactions occurring at a higher incidence (≥2%) in either of the Avastin arms vs the chemotherapy only arm were fatigue (CP+Avastin→Avastin, 9%; CP+Avastin→PBO, 6%; CP+PBO→PBO, 6%), hypertension (CP+Avastin→Avastin, 10%; CP+Avastin→PBO, 6%; CP+PBO→PBO, 2%), platelet count decreased (CP+Avastin→Avastin, 21%; CP+Avastin→PBO, 20%; CP+PBO→PBO, 15%), and white blood cell count decreased (CP+Avastin→Avastin, 51%; CP+Avastin→PBO, 53%; CP+PBO→PBO, 50%)
- In platinum-sensitive recurrent OC, Grade 3 or 4 adverse reactions in the OCEANS study occurring at a higher incidence (≥2%) in 247 patients receiving Avastin plus carboplatin and gemcitabine (chemotherapy), compared to 233 patients receiving placebo plus chemotherapy, were thrombocytopenia (40% vs 34%), nausea (4% vs 1.3%), fatigue (6% vs 4%), headache (4% vs 0.9%), proteinuria (10% vs 0.4%), dyspnea (4% vs 1.7%), epistaxis (5% vs 0.4%), and hypertension (17% vs 0.9%)
- In platinum-sensitive recurrent OC, Grade 3 or 4 adverse reactions in the GOG-0213 study occurring at a higher incidence (≥2%) in 325 patients receiving Avastin plus carboplatin and paclitaxel (chemotherapy), compared to 332 patients receiving chemotherapy alone, were hypertension (11% vs 0.6%), fatigue (8% vs 3%), febrile neutropenia (6% vs 3%), proteinuria (8% vs 0%), abdominal pain (6% vs 0.9%), hyponatremia (4% vs 0.9%), headache (3% vs 0.9%), and pain in extremity (3.4% vs 0%)
- In platinum-resistant recurrent OC, Grade 3–4 adverse reactions in AURELIA occurring at a higher incidence (≥2%) in 179 patients receiving Avastin plus chemotherapy, compared to 181 patients receiving chemotherapy alone, were hypertension (6.7% vs 1.1%) and palmar-plantar erythrodysaesthesia syndrome (4.5% vs 1.7%)

You may report side effects to the FDA at (800) FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Amgen at 1-800-772-6436.

Please see full Prescribing Information for additional important safety information.

INDICATIONS

MVASI® is a vascular endothelial growth factor inhibitor indicated for the treatment of:

MVASI™, in combination with intravenous fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer (mCRC).

MVASI®, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with mCRC who have progressed on a first-line bevacizumab product-containing regimen.

Limitations of Use: MVASI® is not indicated for adjuvant treatment of colon cancer.

MVASI®, in combination with carboplatin and paclitaxel, is indicated for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer (NSCLC).

MVASI® is indicated for the treatment of recurrent glioblastoma (GBM) in adults.

MVASI®, in combination with interferon-alfa, is indicated for the treatment of metastatic renal cell carcinoma (mRCC).

MVASI®, in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer (CC).

MVASI®, in combination with carboplatin and paclitaxel, followed by MVASI as a single agent, is indicated for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection (OC).

MVASI®, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, is indicated for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens (OC).

MVASI®, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by MVASI as a single agent, is indicated for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer (OC).

MVASI®
(bevacizumab-awwb)
Injection 100mg/vial & 400mg/vial

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- Provide payer-specific prior authorization forms

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References: 1. MVASI® (bevacizumab-awwb) Prescribing Information, Amgen. **2.** Centers for Disease Control and Prevention. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2019/icd10cm_index_2019.pdf. Accessed March 4, 2026. **3.** Healthcare Common Procedure Coding System (HCPCS). HCPCS Code Q5107. https://hcpcs.codes/q-codes/Q5107. Accessed March 4, 2026. **4.** American Medical Association. 2017 Professional Edition, Current Procedural Terminology (CPT) copyright 2016 American Medical Association. All rights reserved.

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Please see full Important Safety Information and click here for full Prescribing Information.

Please visit **MVASI.com** for additional information and resources.

Call **1-800-77-AMGEN (1-800-772-6436)** if you have questions about the preparation and administration of MVASI®.

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