

# Resource Guide

MVASI® is a biosimilar to Avastin® (bevacizumab),  
backed by Amgen expertise <sup>1</sup>



## 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

Please see [full Important Safety Information](#) and [click here for full Prescribing Information](#).

## SUPPLY AND STORAGE

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### SUPPLY <sup>1</sup>

MVASI<sup>®</sup> 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<sup>®</sup> contains either:

- **100 mg of MVASI<sup>®</sup>** in 4 mL (25 mg/mL) (NDC 55513-206-01)
- **400 mg of MVASI<sup>®</sup>** in 16 mL (25 mg/mL) (NDC 55513-207-01)

### STORAGE <sup>1</sup>



- Store at 2° to 8°C (36° to 46°F) in the original carton until time of use. MVASI<sup>®</sup> vials should be protected from light.
- Diluted MVASI<sup>®</sup> solutions may be stored at 2° to 8°C (36° to 46°F) for up to 8 hours.



### 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%)

Please see [full Important Safety Information](#) and [click here for full Prescribing Information](#).



# PREPARATION AND ADMINISTRATION

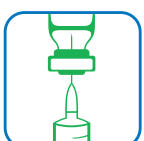
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## DILUTION <sup>1</sup>

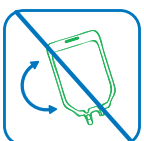
**Use appropriate aseptic technique. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration.**



- MVASI<sup>®</sup> 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<sup>®</sup> 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 <sup>1</sup>

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

- Do not initiate MVASI<sup>®</sup> until at least 28 days following major surgery. Administer MVASI<sup>®</sup> 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  $\geq 3$ , 11% seen in GOG-0240)
  - Hypertension (Grade 3–4, 5%–18%)
  - Posterior reversible encephalopathy syndrome (PRES) (<0.5%)

Please see [full Important Safety Information](#) and [click here for full Prescribing Information](#).

## RECOMMENDED DOSES AND SCHEDULES

METASTATIC COLORECTAL CANCER (mCRC) <sup>1</sup>	
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) <sup>1</sup>	
WITH CARBOPLATIN + PACLITAXEL	Every 3 Weeks 15 mg/kg
RECURRENT GLIOBLASTOMA (rGBM) <sup>1</sup>	
AS SINGLE AGENT	Every 2 Weeks 10 mg/kg
METASTATIC RENAL CELL CARCINOMA (mRCC) <sup>1</sup>	
WITH INTERFERON ALFA	Every 2 Weeks 10 mg/kg
CERVICAL CANCER (CC) <sup>1</sup>	
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.<sup>1</sup>

### 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 with the first dose of bevacizumab occurred in <3% of patients, and severe reactions occurred in 0.4% of patients

Please see [full Important Safety Information](#) and [click here for full Prescribing Information](#).



## CODING

### NATIONAL DRUG CODES (NDCs) <sup>2,3</sup>

<b>BILLING</b>	Each single-dose carton contains one vial of MVASI® (100 mg of bevacizumab-awwb) in 4 mL (25 mg/mL): NDC 55513-206-01
	Each single-dose carton contains one vial of MVASI® (400 mg of bevacizumab-awwb) in 16 mL (25 mg/mL): NDC 55513-207-01

### METASTATIC COLORECTAL CANCER (mCRC)

<b>ICD-10-CM</b> <sup>4</sup>	<b>Malignant neoplasm of the following:</b>	
	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
<b>HCPCS</b> <sup>5</sup>	Q5107 injection, bevacizumab-awwb, 10 mg	
<b>CPT</b> ® <sup>6</sup>	<b>96413:</b> Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	<b>96415:</b> Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	<b>96417:</b> 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

Please see [full Important Safety Information](#) and [click here for full Prescribing Information](#).

## CODING (cont'd)

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

ICD-10-CM <sup>4</sup>	<b>Malignant neoplasm of the following:</b>	
	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 <sup>5</sup>	Q5107 injection, bevacizumab-awwb, 10 mg	
CPT® <sup>6</sup>	<b>96413:</b> Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	<b>96415:</b> Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	<b>96417:</b> 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 <sup>4</sup>	Malignant neoplasm of the brain	C71.0-71.9
HCPCS <sup>5</sup>	Q5107 injection, bevacizumab-awwb, 10 mg	
CPT® <sup>6</sup>	<b>96413:</b> Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	<b>96415:</b> Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	<b>96417:</b> 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

Please see [full Important Safety Information](#) and [click here for full Prescribing Information](#).



## CODING (cont'd)

### METASTATIC RENAL CELL CARCINOMA (mRCC)

	<b>Malignant neoplasm of the following:</b>	
<b>ICD-10-CM</b> <sup>4</sup>	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
<b>HCPCS</b> <sup>5</sup>	Q5107 injection, bevacizumab-awwb, 10 mg	
<b>CPT</b> ® <sup>6</sup>	<b>96413:</b> Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	<b>96415:</b> Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	<b>96417:</b> 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

	<b>Malignant neoplasm of the following:</b>	
<b>ICD-10-CM</b> <sup>4</sup>	Endocervix and exocervix	C53.0-C53.1
	Overlapping sites of cervix uteri and unspecified sites of the cervix uteri	C53.8-C53.9
<b>HCPCS</b> <sup>5</sup>	Q5107 injection, bevacizumab-awwb, 10 mg	
<b>CPT</b> ® <sup>6</sup>	<b>96413:</b> Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug.	
	<b>96415:</b> Chemotherapy administration, intravenous infusion technique; each additional hour. Must be listed separately in addition to code for primary procedure.	
	<b>96417:</b> 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](#).



# HOSPITAL CODING FORM

## The CMS 1450 for Hospital Outpatient

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

1 <b>Anytown Hospital</b> 100 Main Street Anytown, Anystate 01010		2	3a PAT. CNTL. #	4 TYPE OF BILL																					
5 FED. TAX NO.		6 STATEMENT COVERS PERIOD FROM		7 THROUGH																					
8 PATIENT NAME a <b>Smith, Jane</b>		9 PATIENT ADDRESS a <b>123 Main Street, Anytown, Anystate 12345</b>																							
10 BIRTHDATE	11 SEX	12 DATE	ADMISSION 13 HR	14 TYPE	15 SRC	16 DHR	17 STAT	18	19	20	21	CONDITION CODES 22 23 24 25 26 27 28				29 ACDT STATE	30								
31 OCCURRENCE CODE	32 OCCURRENCE DATE	33 OCCURRENCE CODE	34 OCCURRENCE DATE	35 OCCURRENCE CODE	36 OCCURRENCE DATE	OCCURRENCE SPAN FROM		THROUGH		36 OCCURRENCE SPAN FROM		THROUGH		37											
38												39 VALUE CODES		AMOUNT		a		b		c		d			
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE		46 SERV. UNITS		47 TOTAL CHARGES		48 NON-COVERED CHARGES		49											
0636		MVASI bevacizumab-awwb		N4 55513020601		MMDYY		#		XXXMG															
0510		Clinic				MMDYY		#		XXXXX															
PAGE		OF		CREATION DATE		TOTALS																			
50 PAYER NAME				51 HEALTH PLAN ID		52 REL. INFO		53 ASG. BEN.		54 PRIOR PAYMENTS		55 EST. AMOUNT DUE		56 NPI											
57 OTHER PRV ID				58 ICD-10-CM		59 P. REL.		60 INSURED'S UNIQUE ID		61 GROUP NAME		62 INSURANCE GROUP NO.													
63 TREATMENT AUTHORIZATION CODES				64 DOCUMENT CONTROL NUMBER				65 EMPLOYER NAME																	
67		A		B		C		D		E		F		G		H		Q		68					
69 ADMIT DX		70 PATIENT REASON DX		71 PPS CODE		72 ECI		73		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL					
74 PRINCIPAL PROCEDURE CODE		a. OTHER PROCEDURE CODE		b. OTHER PROCEDURE CODE		75		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL		79 OTHER NPI		QUAL			
74 PRINCIPAL PROCEDURE DATE		a. OTHER PROCEDURE DATE		b. OTHER PROCEDURE DATE		75		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL		79 OTHER NPI		QUAL			
74 PRINCIPAL PROCEDURE DATE		a. OTHER PROCEDURE DATE		b. OTHER PROCEDURE DATE		75		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL		79 OTHER NPI		QUAL			
74 PRINCIPAL PROCEDURE DATE		a. OTHER PROCEDURE DATE		b. OTHER PROCEDURE DATE		75		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL		79 OTHER NPI		QUAL			
80 REMARKS		81CC a		b		c		d		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL		79 OTHER NPI		QUAL	
80 REMARKS		81CC a		b		c		d		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL		79 OTHER NPI		QUAL	
80 REMARKS		81CC a		b		c		d		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL		79 OTHER NPI		QUAL	
80 REMARKS		81CC a		b		c		d		76 ATTENDING NPI		QUAL		77 OPERATING NPI		QUAL		78 OTHER NPI		QUAL		79 OTHER NPI		QUAL	

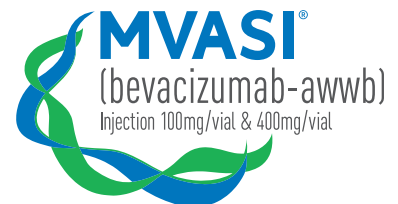
**SERVICE UNITS (BOX 46)**  
Report units of service per MVASI® label and per local payer policy as appropriate.

**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.  
**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®.  
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.

**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.





# 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

55513-206-01

100 mg of MVASI® in 4 mL (25 mg/mL)

One per carton

55513-207-01

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® solutions may be stored at 2° to 8°C (36° to 46°F) for up to 8 hours. 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 Assist 360™: 1-888-4ASSIST (1-888-427-7478) or [www.AmgenAssistOnline.com](http://www.AmgenAssistOnline.com)

Please see [full Important Safety Information](#) and [click here for full Prescribing Information](#).



# 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  $\geq 3$ , 5%, highest in patients with GBM)
  - The incidence of wound healing and surgical complications, including serious and fatal complications, is increased in MVASI<sup>®</sup>-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  $\geq 3$ , 11% seen in GOG-0240)
  - Hypertension (Grade 3–4, 5%–18%)
  - Posterior reversible encephalopathy syndrome (PRES) (<0.5%)
  - Congestive heart failure (CHF): Grade  $\geq 3$  left ventricular dysfunction (1%)
- 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<sup>®</sup>

## Pregnancy warning

- Based on the mechanism of action and animal studies, MVASI<sup>®</sup> may cause fetal harm
- Advise female patients that MVASI<sup>®</sup> 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<sup>®</sup> and for 6 months after the last dose of MVASI<sup>®</sup>
- Advise nursing women not to breastfeed during treatment with MVASI<sup>®</sup> and for 6 months following their last dose of treatment
- MVASI<sup>®</sup> 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 ( $\geq 2\%$ ) 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  $\geq 2\%$  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  $\geq 2\%$  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 ( $\geq 2\%$ ) 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 ( $\geq 2\%$ ) 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 ( $\geq 2\%$ ) 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 ( $\geq 2\%$ ) 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 ( $\geq 2\%$ ) in 179 patients receiving Avastin plus chemotherapy, compared to 181 patients receiving chemotherapy alone, were hypertension (6.7% vs 1.1%) and palmar-plantar erythrodysesthesia syndrome (4.5% vs 1.7%)

You may report side effects to the FDA at (800) FDA-1088 or [www.fda.gov/medwatch](http://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).







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**References:** **1.** MVASI® (bevacizumab-awwb) Prescribing Information, Amgen. **2.** National Drug Codes List. NDC 55513-206-01 MVASI. <https://ndclist.com/ndc/55513-206/package/55513-206-01>. Accessed March 25, 2019. **3.** National Drug Codes List. NDC 55513-207-01 MVASI. <https://ndclist.com/ndc/55513-207/package/55513-207-01>. Accessed March 25, 2019. **4.** Centers for Disease Control and Prevention. International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM). [ftp://ftp.cdc.gov/pub/Health\\_Statistics/NCHS/Publications/ICD10CM/2019/icd10cm\\_index\\_2019.pdf](ftp://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2019/icd10cm_index_2019.pdf). Accessed March 25, 2019. **5.** Healthcare Common Procedure Coding System (HCPCS). HCPCS Code Q5107. <https://hcpcs.codes/q-codes/Q5107>. Accessed March 25, 2019. **6.** 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](http://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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