

VEGZELMA® (bevacizumab-adcd) Sample Coding Metastatic Renal Cell Carcinoma (mRCC)



This tip sheet serves as an educational reference for codes that may be appropriate for reporting VEGZELMA and related services. Medical record documentation must support the codes reported on the claim. The following codes may be appropriate when VEGZELMA is administered as combination therapy in patients with mRCC in outpatient sites of care:

Code Set	Code and Description	Site of Care	
		MDO	HOPD
ICD-10-CM ¹	C64.1-C64.9 Malignant neoplasm of kidney, except renal pelvis	✓	✓
	C65.1-C65.9 Malignant neoplasm of renal pelvis	✓	✓
	Z51.11 Encounter for antineoplastic chemotherapy	✓	✓

One or more codes may be appropriate on claims. Please review payer policy requirements for guidance on diagnosis codes.

HCPCS ²	Q5129 Injection, bevacizumab-adcd (vegzelma), biosimilar, 10 mg	✓	✓
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Q5129 is effective for claims with dates of service on/after April 1, 2023.

NDC ³	72606-0011-01 (100 mg/4 mL, carton of 1 single-dose vial)	✓	✓
	72606-0012-01 (400 mg/16 mL, carton of 1 single-dose vial)	✓	✓

The 11-digit NDC is required on the claim form. The “N4” qualifier is required before the NDC. The NDC unit of measure (UOM) qualifier and quantity may also be required.^{4,5} Check payer-specific reporting requirements.

HCPCS Modifiers ²	JW Drug amount discarded/not administered to any patient	✓	✓
	JZ Zero drug amount discarded/not administered to any patient	✓	✓
	JG Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes <i>(Use for drugs without temporary pass-through payment status)</i>	NA	✓
	TB Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities <i>(Use for drugs with temporary pass-through payment status)</i>	NA	✓

HCPCS – Healthcare Common Procedure Coding System; HOPD – hospital outpatient department; ICD-10-CM – International Classification of Diseases, 10th Revision, Clinical Modification; MDO – medical doctor’s office (physician office); NDC – National Drug Code; UOM – unit of measure.

Select Important Safety Information

ADVERSE REACTIONS BY INDICATION

Metastatic renal cell carcinoma in combination with interferon alfa

Study BO17705: Grades 3-5 adverse reactions occurring at a higher incidence (>2%) in patients receiving bevacizumab with interferon alfa (N=337) vs placebo with interferon alfa (N=304) 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).³

Refer to the accompanying VEGZELMA Full Prescribing Information, including Important Safety Information on pages 3 and 4.

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Code Set	Code and Description	Site of Care	
		MDO	HOPD
CPT ⁶	96413 Chemotherapy administration, intravenous infusion technique; up to 1 hour, single or initial substance/drug	✓	✓
	96415 Chemotherapy administration, intravenous infusion technique; each additional hour (List separately in addition to code for primary procedure)	✓	✓
	96417 Chemotherapy administration, intravenous infusion technique; each additional sequential infusion (different substance/drug), up to 1 hour (List separately in addition to code for primary procedure)	✓	✓

VEGZELMA intravenous (IV) infusion lasting 30-60-90 minutes may be reported with 96413 or 96417. In addition, CPT 96415 is also reported for an IV infusion lasting at least 91 minutes.

Revenue Codes ⁷ Other revenue codes may apply	VEGZELMA	0636 Drugs requiring detailed coding	NA	✓
		Administration	0260 IV therapy, general	NA

CPT – Current Procedural Terminology; IV – intravenous.

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References: **1.** CMS. FY2023 ICD-10-CM tabular. Updated January 11, 2023. Accessed March 13, 2023. <https://www.cms.gov/medicare/icd-10/2023-icd-10-cm> **2.** CMS. HCPCS quarterly update. April 2023 alpha-numeric HCPCS file. March 8, 2023. Accessed March 13, 2023. <https://www.cms.gov/medicare/coding/hcpcsrleasecodesets/hcpcs-quarterly-update> **3.** Vegzelma Prescribing Information. Celltrion USA, Inc.; 2023. **4.** MCPM. Chapter 26 – Completing and processing Form CMS-1500 data set. Updated May 27, 2022. Accessed March 13, 2023. <https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/clm104c26pdf.pdf> **5.** MCPM. Chapter 25 – Completing and processing the Form CMS-1450 data set. Updated August 6, 2021. Accessed March 13, 2023. <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf> **6.** American Medical Association. 2023 Professional Edition, Current Procedural Terminology (CPT) copyright 2022 American Medical Association. All rights reserved. **7.** Noridian Healthcare Solutions. Revenue codes. Updated June 28, 2022. Accessed March 13, 2023. <https://med.noridianmedicare.com/web/jea/topics/claim-submission/revenue-codes>

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Important Safety Information

WARNINGS AND PRECAUTIONS

Gastrointestinal Perforations and Fistulae: Serious, and sometimes fatal, gastrointestinal perforation occurred at a higher incidence in patients receiving bevacizumab products vs chemotherapy. The incidence ranged from 0.3% to 3% across clinical studies, with the highest incidence in patients with a history of prior pelvic radiation. Serious fistulae ranged from <1% to 1.8% across clinical studies, with the highest incidence in patients with cervical cancer. Avoid VEGZELMA 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. Discontinue in patients who develop gastrointestinal perforation, tracheoesophageal fistula, or any Grade 4 fistula. Discontinue in patients with fistula formation involving any internal organ.

Surgery and Wound Healing Complications: The incidence of surgery and wound healing complications, including serious and fatal complications, was increased in patients receiving bevacizumab products. In patients who experience wound healing complications during treatment, withhold VEGZELMA until adequate wound healing. Discontinue VEGZELMA in patients who develop necrotizing fasciitis.

Hemorrhage: Severe or fatal hemorrhage occurred up to 5-fold more frequently in patients receiving bevacizumab products vs chemotherapy alone. Discontinue VEGZELMA in patients who develop a Grades 3-4 hemorrhage.

Arterial Thromboembolic Events: Serious, sometimes fatal, arterial thromboembolic events (ATE) occurred at a higher incidence in patients receiving bevacizumab vs chemotherapy. Discontinue VEGZELMA in patients who develop a severe ATE. The safety of reinitiating bevacizumab products after an ATE is resolved is not known.

Venous Thromboembolic Events: An increased risk of venous thromboembolic events (VTE) was observed across clinical studies. Discontinue VEGZELMA in patients with a Grade 4 VTE, including pulmonary embolism.

Hypertension: Severe hypertension occurred at a higher incidence in patients receiving bevacizumab products vs chemotherapy alone. Monitor blood pressure every two to three weeks during treatment with VEGZELMA. Treat with appropriate anti-hypertensive therapy and monitor blood pressure regularly. Discontinue in patients who develop hypertensive crisis or hypertensive encephalopathy.

Posterior Reversible Encephalopathy Syndrome: Posterior reversible encephalopathy syndrome (PRES) was reported in <0.5% of patients across clinical studies. Discontinue VEGZELMA in patients who develop PRES.

Renal Injury and Proteinuria: The incidence and severity of proteinuria was higher in patients receiving bevacizumab products vs chemotherapy. Nephrotic syndrome occurred in <1% of patients receiving bevacizumab products across clinical studies, in some instances with fatal outcome. Discontinue VEGZELMA in patients who develop nephrotic syndrome.

Infusion-Related Reactions: In clinical studies, infusion-related

reactions with the first dose of bevacizumab products occurred in <3% of patients and severe reactions occurred in 0.4% of patients. Decrease the rate of infusion for mild, clinically insignificant infusion-related reactions. Interrupt the infusion in patients with clinically significant infusion-related reactions and consider resuming at a slower rate following resolution. Discontinue VEGZELMA in patients who develop a severe infusion-related reaction and administer appropriate medical therapy.

Embryo-Fetal Toxicity: Bevacizumab products may cause fetal harm when administered to pregnant women. Advise pregnant women of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment with VEGZELMA and for 6 months after the last dose.

Ovarian Failure: The incidence of ovarian failure was 34% vs 2% in premenopausal women receiving bevacizumab with chemotherapy vs chemotherapy alone for adjuvant treatment of a solid tumor. Inform females of reproductive potential of the risk of ovarian failure prior to initiating treatment with VEGZELMA.

Congestive Heart Failure (CHF): VEGZELMA is not indicated for use with anthracycline-based chemotherapy. Discontinue VEGZELMA in patients who develop CHF.

MOST COMMON ADVERSE REACTIONS

The most common adverse reactions observed in patients receiving bevacizumab products as a single agent or in combination with other anti-cancer therapies at a rate >10% were epistaxis, headache, hypertension, rhinitis, proteinuria, taste alteration, dry skin, hemorrhage, lacrimation disorder, back pain, and exfoliative dermatitis.

Across clinical studies, bevacizumab was discontinued in 8% to 22% of patients because of adverse reactions.

ADVERSE REACTIONS BY INDICATION

Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment

- **Study AVF2107g:** Grades 3-4 adverse reactions occurring at higher incidence ($\geq 2\%$) in patients receiving bevacizumab with IFL (N=392) vs placebo with IFL (N=396) were leukopenia (37% vs 31%), neutropenia (21% vs 14%), diarrhea (34% vs 25%), abdominal pain (8% vs 5%), constipation (4% vs 2%), hypertension (12% vs 2%), deep vein thrombosis (9% vs 5%), intra-abdominal thrombosis (3% vs 1%), syncope (3% vs 1%), asthenia (10% vs 7%), and pain (8% vs 5%)

Important Safety Information (cont.)

WARNINGS AND PRECAUTIONS (cont.)

ADVERSE REACTIONS BY INDICATION (cont.)

Metastatic colorectal cancer, in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen

- **Study E3200:** Selected Grades 3–5 (non-hematologic) and Grades 4–5 (hematologic) reactions occurring at a higher incidence ($\geq 2\%$) in patients receiving bevacizumab with FOLFOX4 (N=521) vs FOLFOX4 alone 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%)

Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment

- **Study E4599:** Grades 3-5 (non-hematologic) and Grades 4-5 (hematologic) adverse reactions occurring at a higher incidence ($\geq 2\%$) in patients receiving bevacizumab with paclitaxel and carboplatin (N=422) vs chemotherapy alone 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%)

Recurrent glioblastoma in adults

- **Study EORTC 26101:** In the bevacizumab with lomustine arm (N=278), 22% of patients discontinued treatment due to adverse reactions vs 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

Metastatic renal cell carcinoma in combination with interferon alfa

- **Study BO17705:** Grades 3-5 adverse reactions occurring at a higher incidence ($> 2\%$) in patients receiving bevacizumab with interferon alfa (N=337) vs placebo with interferon alfa (N=304) 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)

Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan

- **Study GOG-0240:** Grades 3-4 adverse reactions occurring at a higher incidence ($\geq 2\%$) in patients receiving bevacizumab with chemotherapy (N=218) vs chemotherapy alone (N=222) were abdominal pain (12% vs 10%), hypertension (11% vs 0.5%), thrombosis (8% vs 3%), 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%), 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%)

Epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel, followed by VEGZELMA as a single agent, for stage III or IV disease following initial surgical resection

- **Study GOG-0218:** Grades 3-4 adverse reactions occurring at a higher incidence ($\geq 2\%$) in either of the bevacizumab arms (N=608, N=607) vs control arm (N=602) were fatigue (CPB15+ - 9%, CPB15 - 6%, CPP - 6%), hypertension (CPB15+ - 10%, CPB15 - 6%, CPP - 2%), thrombocytopenia (CPB15+ - 21%, CPB15 - 20%, CPP - 15%), and leukopenia (CPB15+ - 51%, CPB15 - 53%, CPP - 50%)

Epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens

- **Study MO22224:** Grades 3-4 adverse reactions occurring at a higher incidence ($\geq 2\%$) in patients receiving bevacizumab with chemotherapy (N=179) vs chemotherapy alone (N=181) were hypertension (6.7% vs 1.1%) and palmar-plantar erythrodysesthesia syndrome (4.5% vs 1.7%)

Epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with carboplatin and paclitaxel or carboplatin and gemcitabine, followed by VEGZELMA as a single agent, for platinum-sensitive recurrent disease

- **Study AVF4095g:** Grades 3-4 adverse reactions occurring at a higher incidence ($\geq 2\%$) in patients receiving bevacizumab with chemotherapy (N=247) vs placebo with chemotherapy (N=233) 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%)

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch or call 1-800-FDA-1088.

Please see full Prescribing Information for complete information.

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