

Indication

Vectibix® is indicated for the treatment of patients with wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS* as determined by an FDA-approved test for this use) metastatic colorectal cancer (mCRC):

- As first-line therapy in combination with FOLFOX.
- As monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.

Limitation of Use

Vectibix® is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.

Item	Revenue Code ^{1,2}	Coding Information (HCPCS ³ /CPT ⁴ /ICD-10-CM ⁵)	Notes
Vectibix®	Medicare: 0636, drugs requiring detailed coding ⁶	J9303, injection, panitumumab, 10 mg	Vectibix® is supplied in single-use vials containing 100 mg in 5 mL (20 mg/mL), 200 mg in 10 mL (20 mg/mL), and 400 mg in 20 mL (20 mg/mL) of panitumumab The NDC numbers for Vectibix®, in the 11-digit format, are as follows: - 5-mL vial: 55513-0954-01 - 10-mL vial: 55513-0955-01 - 20-mL vial: 55513-0956-01
	Other Payers: 0250, general pharmacy; OR 0636, if required by a given payer ⁶		
Administration	Appropriate revenue code for the cost center in which the service is performed	96413, chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug* 96415, each additional hour (list separately in addition to code for primary procedure)	In addition to 96413, report 96415 when the infusion interval is > 30 minutes beyond the 1 hour represented by 96413
Diagnosis/Condition	N/A	Appropriate ICD-10-CM code(s) for patient condition	Example: C18.4 Malignant neoplasm of the transverse colon

* The recommended dose of Vectibix® is 6 mg/kg, administered as an intravenous infusion over 60 minutes, every 14 days. Doses higher than 1,000 mg should be administered over 90 minutes.

1. Value Healthcare Services. Understanding Hospital Revenue Codes. 2014. Available at: <http://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/>. Accessed August 6, 2014.

2. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual - Chapter 25. Completing and Processing the Form CMS-1450 Data Set. Available at: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf>. Accessed August 6, 2014.

3. Centers for Medicare & Medicaid Services. 2015 Alpha-Numeric HCPCS File. Available at: <http://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/Alpha-Numeric-HCPCS-Items/2015-Alpha-Numeric-HCPCS-File-%C2%A0.html>. Accessed May 29, 2015.

4. American Medical Association. Current Procedural Terminology (CPT®) copyright 2014 American Medical Association. 2015. All Rights Reserved.

5. Centers for Medicare & Medicaid Services. 2015 ICD-10-CM Tabular List of Diseases and Injuries. Available at: <http://www.cdc.gov/nchs/icd/icd10cm.htm#icd2016>. Accessed July 23, 2015.

6. Centers for Medicare & Medicaid Services. Publication 100-04: Medicare Claims Processing Manual, Chapter 17: Drugs and Biologicals, Section 80.9: Required Modifiers for ESAs Administered to Non-ESRD Patients. Available at: <http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf>. Accessed August 6, 2014.

The information provided in this document is of a general nature and for informational purposes only; it is not intended to be comprehensive or instructive. Coding and coverage policies change periodically and often without warning. The healthcare provider is solely responsible for determining coverage and reimbursement parameters and appropriate coding for his/her own patients and procedures. In no way should the information provided in this section be considered a guarantee of coverage or reimbursement for any product or service.

WARNING: DERMATOLOGIC TOXICITY

Dermatologic Toxicity: Dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients receiving Vectibix® monotherapy [See *Dosage and Administration (2.3)*, *Warnings and Precautions (5.1)*, and *Adverse Reactions (6.1)*].

Contact Amgen Assist® at 1-888-4ASSIST for assistance.
www.AmgenAssistOnline.com

Please see Important Safety Information, including Boxed WARNING, on pages 3 and 4.



The CMS 1450 for Hospital Outpatient

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

1 Anytown Hospital 100 Main Street Anytown, Anystate 01010		2		3a PAT. CNTRL. # b. MED. REC. #		4 TYPE OF BILL	
8 PATIENT NAME Smith, Jane		9 PATIENT ADDRESS 123 Main Street, Anytown, Anystate 12345					
10 BIRTHDATE		11 SEX		12 DATE		13 HR	
14 TYPE		15 SRC		16 DHR		17 STAT	
18		19		20		21	
22		23		24		25	
26		27		28		29	
30		31		32		33	
34		35		36		37	
38		39		40		41	
42 REV. CD.		43 DESCRIPTION		44 HCPCS / RATE / HIPPS CODE		45 SERV. DATE	
0636		Drugs/detailed coding		J9303		MDDYY X	
0250		General pharmacy		96413		MDDYY XXXXX	
46		47		48		49	
50		51		52		53	
54		55		56		57	
58		59		60		61	
62		63		64		65	
66		67		68		69	
70		71		72		73	
74		75		76		77	
78		79		80		81	
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94		95		96		97	
98		99		00		01	

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).

PRODUCT AND PROCEDURE CODES (BOX 44)

Product
Use J9303, injection, panitumumab, 10 mg.

Related administration procedure
Use CPT code representing procedure performed, such as 96413, chemotherapy administration, IV infusion technique; up to 1 hour, single or initial substance/drug.

SERVICE UNITS (BOX 46)

Report units of service.
1 unit for J9303 corresponds to 10 mg of Vectibix®.

TOTAL CHARGES (BOX 47)

Report appropriate charges for product used and related procedures.

DIAGNOSIS CODES (BOX 67)

Enter appropriate ICD-10-CM diagnosis code(s) corresponding to patient's diagnosis, eg, C18.4, malignant neoplasm of the transverse colon.

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.

Please see Important Safety Information, including Boxed WARNING, on pages 3 and 4.

WARNING: DERMATOLOGIC TOXICITY
Dermatologic Toxicity: Dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients receiving Vectibix® monotherapy [See Dosage and Administration (2.3), Warnings and Precautions (5.1), and Adverse Reactions (6.1)].

In Study 20020408, dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients with mCRC receiving Vectibix®. The clinical manifestations included, but were not limited to, acneiform dermatitis, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures.

Monitor patients who develop dermatologic or soft tissue toxicities while receiving Vectibix® for the development of inflammatory or infectious sequelae. Life-threatening and fatal infectious complications including necrotizing fasciitis, abscesses, and sepsis have been observed in patients treated with Vectibix®. Life-threatening and fatal bullous mucocutaneous disease with blisters, erosions, and skin sloughing has also been observed in patients treated with Vectibix®. It could not be determined whether these mucocutaneous adverse reactions were directly related to EGFR inhibition or to idiosyncratic immune-related effects (eg, Stevens Johnson syndrome or toxic epidermal necrolysis). Withhold or discontinue Vectibix® for dermatologic or soft tissue toxicity associated with severe or life-threatening inflammatory or infectious complications. Dose modifications for Vectibix® concerning dermatologic toxicity are provided in the product labeling.

Vectibix® is not indicated for the treatment of patients with colorectal cancer that harbor somatic *RAS* mutations in exon 2 (codons 12 and 13), exon 3 (codons 59 and 61), and exon 4 (codons 117 and 146) of either *KRAS* or *NRAS* and hereafter is referred to as “*RAS*.”

Retrospective subset analyses across several randomized clinical trials were conducted to investigate the role of *RAS* mutations on the clinical effects of anti-EGFR-directed monoclonal antibodies (panitumumab or cetuximab). Anti-EGFR antibodies in patients with tumors containing *RAS* mutations resulted in exposing those patients to anti-EGFR related adverse reactions without clinical benefit from these agents. Additionally, in Study 20050203, 272 patients with *RAS*-mutant mCRC tumors received Vectibix® in combination with FOLFOX and 276 patients received FOLFOX alone. In an exploratory subgroup analysis, OS was shorter (HR = 1.21, 95% CI: 1.01-1.45) in patients with *RAS*-mutant mCRC who received Vectibix® and FOLFOX versus FOLFOX alone.

Progressively decreasing serum magnesium levels leading to severe (grade 3-4) hypomagnesemia occurred in up to 7% (in Study 20080763) of patients across clinical trials. Monitor patients for hypomagnesemia and hypocalcemia prior to initiating Vectibix® treatment, periodically during Vectibix® treatment, and for up to 8 weeks after the completion of treatment. Other electrolyte disturbances, including hypokalemia, have also been observed. Replete magnesium and other electrolytes as appropriate.

In Study 20020408, 4% of patients experienced infusion reactions and 1% of patients experienced severe infusion reactions (NCI-CTC grade 3-4). Infusion reactions, manifesting as fever, chills, dyspnea, bronchospasm, and hypotension, can occur following Vectibix® administration. Fatal infusion reactions occurred in postmarketing experience. Terminate the infusion for severe infusion reactions.

Severe diarrhea and dehydration, leading to acute renal failure and other complications, have been observed in patients treated with Vectibix® in combination with chemotherapy.

Fatal and nonfatal cases of interstitial lung disease (ILD) (1%) and pulmonary fibrosis have been observed in patients treated with Vectibix®. Pulmonary fibrosis occurred in less than 1% (2/1467) of patients enrolled in clinical studies of Vectibix®. In the event of acute onset or worsening of pulmonary symptoms interrupt Vectibix® therapy. Discontinue Vectibix® therapy if ILD is confirmed.

In patients with a history of interstitial pneumonitis or pulmonary fibrosis, or evidence of interstitial pneumonitis or pulmonary fibrosis, the benefits of therapy with Vectibix® versus the risk of pulmonary complications must be carefully considered.

Exposure to sunlight can exacerbate dermatologic toxicity. Advise patients to wear sunscreen and hats and limit sun exposure while receiving Vectibix®.

Keratitis and ulcerative keratitis, known risk factors for corneal perforation, have been reported with Vectibix® use. Monitor for evidence of keratitis or ulcerative keratitis. Interrupt or discontinue Vectibix® for acute or worsening keratitis.

Please see enclosed Vectibix® package insert for full Prescribing Information, including Boxed WARNING.



In an interim analysis of an open-label, multicenter, randomized clinical trial in the first-line setting in patients with mCRC, the addition of Vectibix® to the combination of bevacizumab and chemotherapy resulted in decreased OS and increased incidence of NCI-CTC grade 3-5 (87% vs 72%) adverse reactions. NCI-CTC grade 3-4 adverse reactions occurring at a higher rate in Vectibix®-treated patients included rash/acneiform dermatitis (26% vs 1%), diarrhea (23% vs 12%), dehydration (16% vs 5%), primarily occurring in patients with diarrhea, hypokalemia (10% vs 4%), stomatitis/mucositis (4% vs < 1%), and hypomagnesemia (4% vs 0).

NCI-CTC grade 3-5 pulmonary embolism occurred at a higher rate in Vectibix®-treated patients (7% vs 3%) and included fatal events in three (< 1%) Vectibix®-treated patients. As a result of the toxicities experienced, patients randomized to Vectibix®, bevacizumab, and chemotherapy received a lower mean relative dose intensity of each chemotherapeutic agent (oxaliplatin, irinotecan, bolus 5-FU, and/or infusional 5-FU) over the first 24 weeks on study compared with those randomized to bevacizumab and chemotherapy.

Vectibix® can cause fetal harm when administered to a pregnant woman. Advise pregnant women and females of reproductive potential of the potential risk to a fetus. Advise females of reproductive potential to use effective contraception during treatment, and for at least 2 months after the last dose of Vectibix®.

In monotherapy, the most commonly reported adverse reactions (≥ 20%) in patients with Vectibix® were skin rash with variable presentations, paronychia, fatigue, nausea, and diarrhea.

The most commonly reported adverse reactions (≥ 20%) with Vectibix® + FOLFOX were diarrhea, stomatitis, mucosal inflammation, asthenia, paronychia, anorexia, hypomagnesemia, hypokalemia, rash, acneiform dermatitis, pruritus, and dry skin. The most common serious adverse reactions (≥ 2% difference between treatment arms) were diarrhea and dehydration.

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