INDICATION:

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

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

LIMITATIONS OF USE:

Vectibix® is not indicated for the treatment of patients with *RAS*-mutant mCRC unless used in combination with sotorasib in *KRAS* G12C-mutated mCRC. Vectibix® is not indicated for the treatment of patients with mCRC for whom *RAS* mutation status is unknown.

For information about the use of Vectibix® in combination with sotorasib, see Vectibix® Prescribing Information.

Item	Revenue Code[1,2]	Coding Information (HCPCS[3]/CPT[4]/ICD-10-CM[5])	Notes
Vectibix®	**Medicare:** 0636, drugs requiring detailed coding[6] **Other Payers:** 0250, general pharmacy; **OR** 0636, if required by a given payer[6]	J9303, injection, panitumumab, 10 mg **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. Additional provider types will be required to use these modifiers in 2024[7]. **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."[8]	Vectibix® is supplied in single-use vials containing 100 mg in 5 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, 55513-0954-21 - 20-mL vial: 55513-0956-01, 55513-0956-21
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

Call Amgen® SupportPlus at 1-866-264-2778 Monday - Friday 8:30 am – 8:00 pm ET.
Visit AmgenSupportPlus.com to learn how Amgen can help.

NOTE: Reporting policies for discarded units for payers other than traditional fee-for-service Medicare may vary; providers should check with their specific plans about policies related to billing for discarded drug and use of the JW and JZ modifiers.

*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. Accessed May 31, 2023. http://valuehealthcareservices.com/education/understanding-hospital-revenue-codes/

2. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual - Chapter 25. Completing and Processing the Form CMS-1450 Data Set. Rev 4194. Accessed May 31, 2023. https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c25.pdf

3. Centers for Medicare & Medicaid Services. July 2021 Alpha-Numeric HCPCS File. Page last modified July 23, 2021. Accessed May 31, 2023. https://www.cms.gov/Medicare/Coding/HCPCSReleaseCodeSets/HCPCS-Quarterly-Update

4. American Medical Association. Current Procedural Terminology (CPT®) 2021 Professional Edition. Copyright 2020. All rights reserved.

5. Centers for Disease Control and Prevention. ICD-10-CM FY 2022 List of Codes and Descriptions. Accessed May 31, 2023. https://ftp.cdc.gov/pub/Health_Statistics/NCHS/Publications/ICD10CM/2022/

6. Centers for Medicare & Medicaid Services. Medicare Claims Processing Manual - Chapter 17: Drugs and Biologicals. Rev 10329. Accessed May 31, 2023. http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/clm104c17.pdf

7. CMS, Part B Inflation Rebate Guidance: Use of the 340B Modifiers, December 20, 2022, available at https://www.cms.gov/files/document/part-b-inflation-rebate-guidance340b-modifierfinal.pdf. Accessed May 31, 2023.

8. CMS, Discarded Drugs and Biologicals – JW Modifier and JZ Modifier Policy, available at https://www.cms.gov/medicare/medicare-fee-for-service-payment/hospitaloutpatientpps/downloads/jw-modifier-faqs.pdf. Accessed May 31, 2023.

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.

BOXED WARNING: DERMATOLOGIC TOXICITY

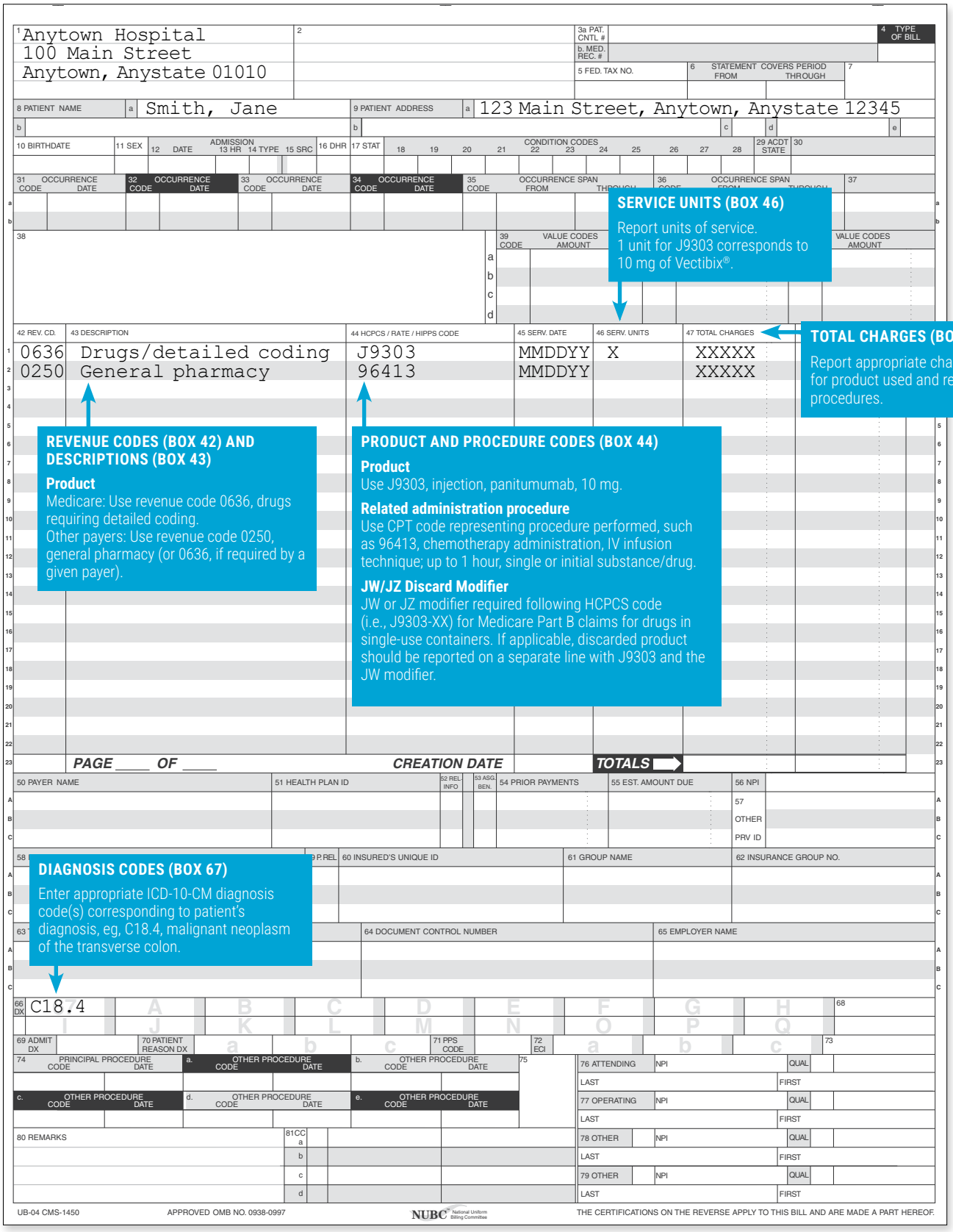
Dermatologic Toxicity: Dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC Grade 3 and higher) in 15% of patients receiving Vectibix® monotherapy

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

Vectibix® (panitumumab) Injection for IV Infusion

The CMS 1450 for Hospital Outpatient

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



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.

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- Vectibix® can cause dermatologic toxicity, which may be severe. Clinical manifestations included, but were not limited to, acneiform dermatitis, pruritus, erythema, rash, skin exfoliation, paronychia, dry skin, and skin fissures.
- Among 229 patients who received Vectibix® as monotherapy, dermatologic toxicity occurred in 90% including Grade 3 (15%). Among 585 patients who received Vectibix® in combination with FOLFOX, dermatologic toxicity occurred in 96% including Grade 4 (1%) and Grade 3 (32%). In 126 patients receiving Vectibix® in combination with sotorasib across clinical studies, dermatologic toxicities occurred in 94%, including Grade 3 (16%) of patients.
- 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 *[see Dosage and Administration (2.3)]*.
- Vectibix® monotherapy or in combination with oxaliplatin-based chemotherapy 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.
- Vectibix® can cause progressively decreasing serum magnesium levels leading to severe (Grade 3 or 4) hypomagnesemia. Among 229 patients who received Vectibix® as monotherapy, hypomagnesemia occurred in 38% including Grade 4 (1.3%) and Grade 3 (2.6%). Among 585 patients who received Vectibix® in combination with FOLFOX, hypomagnesemia occurred in 51% including Grade 4 (5%) and Grade 3 (6%). In 126 patients receiving Vectibix® in combination with sotorasib across clinical studies, decreased magnesium occurred in 69%, including Grade 4 (2.4%) and Grade 3 (14%).
- 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®. Among 229 patients who received Vectibix® as monotherapy, acute renal failure occurred in 2% including Grades 3 or 4 (2%). Among 585 patients who received Vectibix® in combination with FOLFOX, acute renal failure occurred in 2% including Grade 3 or 4 (2%). In 126 patients receiving Vectibix® in combination with sotorasib across clinical studies, acute renal failure occurred in 3.2%, including Grade 3 (0.8%). Monitor patients for diarrhea and dehydration, provide supportive care (including anti-emetic or anti-diarrheal therapy) as needed, and withhold Vectibix® if necessary.

Please click here to see Vectibix® full Prescribing Information, including Boxed WARNING.

Vectibix® (panitumumab) Injection for IV Infusion

- 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®. Grade 1 ILD/pneumonitis occurred in 0.8% (1/126) of patients enrolled in clinical studies of Vectibix® in combination with sotorasib. 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®.

- Serious cases of keratitis, ulcerative keratitis, and corneal perforation have occurred with Vectibix® use. Among 585 patients who received Vectibix® in combination with FOLFOX, keratitis occurred in 0.3%. In 126 patients receiving Vectibix® in combination with sotorasib across clinical studies, keratitis occurred in 1.6%, ulcerative keratitis occurred in 0.8%, and vernal keratoconjunctivitis in 0.8% (all were Grade 1-2). Monitor for evidence of keratitis, ulcerative keratitis, or corneal perforation. Interrupt or discontinue Vectibix® therapy for acute or worsening keratitis, ulcerative keratitis, or corneal perforation.

- 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.

- Based on data from animal studies and its mechanism of action, Vectibix® can cause fetal harm when administered to a pregnant woman. When given during organogenesis, panitumumab administration resulted in embryolethality in cynomolgus monkeys at exposures approximately 1.25 to 5 times the recommended human dose. Advise pregnant women and females of reproductive potential of the potential risk to the 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. Serious adverse reactions (≥ 2% difference between treatment arms) were diarrhea and dehydration.

Please click here to see Vectibix® full Prescribing Information, including Boxed WARNING.

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Vectibix® (panitumumab)
Injection for IV Infusion