Vectibix® (panitumumab)
100mg/5ml | 20mg/ml for injection

ELECTRONIC MEDICAL RECORD/ PRACTICE MANAGEMENT SYSTEM TIP SHEET

This tool provides a few examples of queries on electronic medical records and/or practice management systems that may be helpful in identifying appropriate patients for Vectibix® (panitumumab). This tool should not be used for coding or reimbursement.*

THE NCCN CLINICAL PRACTICE GUIDELINES IN ONCOLOGY (NCCN GUIDELINES®) FOR COLON CANCER AND RECTAL CANCER RECOMMEND PANITUMUMAB (VECTIBIX®) + FOLFOX AS A FIRST-LINE TREATMENT OPTION FOR CERTAIN PATIENTS† WITH WT RAS mCRC[1,2,‡]

NCCN=National Comprehensive Cancer Network® (NCCN®)
*These examples are not intended to be instructive with respect to clinical decision-making or billing and coding. Healthcare providers are solely responsible for clinical decisions and ensuring the accuracy and validity of all billing and claims. This is not a guarantee of coverage or reimbursement for any product or service.
†See the guidelines online at NCCN.org for the full recommendation.
‡NCCN makes no warranties of any kind whatsoever regarding their content, use or application and disclaims any responsibility for their application or use in any way.

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 *[See Dosage and Administration (2.3), Warnings and Precautions (5.1), and Adverse Reactions (6.1)].*

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.

Please see full Important Safety Information, including Boxed WARNING, on page 3.

INFORMATION FOR PATIENTS WITH METASTATIC COLORECTAL CANCER (mCRC)

REQUIREMENTS	SEARCH CRITERIA TO CONSIDER	HELPFUL SEARCH TIPS
Evidence of wild-type *RAS*	• Evidence of mCRC wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS*, as determined by an FDA-approved test for this use). CPT codes for FDA-approved tests for this use include*: ° 81275-81276 or 81311 for gene analysis ° 81405 for molecular pathology procedure	• Establishing evidence of wild-type *RAS* and additional criteria as listed below may require patient chart review • Vectibix® is not indicated for patients with *RAS*-mutant mCRC or for whom *RAS* mutation is unknown
IF confirmed wild-type *RAS*: **Confirmation and location of mCRC**	**mCRC** • C18.0-C20 • C21.8 • C78.5 • D37.4 • D37.5	• Establishing evidence of wild-type *RAS* and confirming lack of therapy for metastatic disease may require patient chart review • ICD-10-CM codes may be used to identify patients with mCRC
	Left Side • C21.8 • C78.5 • D37.4 • D37.5	• ICD-10-CM codes may be used to identify location of primary tumor
IF confirmed wild-type *RAS* and mCRC: **As first-line therapy in combination with FOLFOX**	• All of the following HCPCS codes for concurrent FOLFOX therapy within the past 4 weeks: ° J9263 for oxaliplatin ° J9190 for fluorouracil (5-FU) ° J0640 for leucovorin	• Establishing evidence of wild-type *RAS* and confirming lack of therapy for metastatic disease may require patient chart review • Vectibix® is not indicated for patients with *RAS*-mutant mCRC or for whom *RAS* mutation is unknown • These patients include those who are treatment-naïve • HCPCS codes may be used to identify patients who are concurrently treated with FOLFOX
IF confirmed wild-type *RAS* and mCRC: **As monotherapy following disease progression after having tried and failed prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy**	• Previously tried and failed the following therapies: ° J9190 for fluorouracil (5-FU) ° J9263 for oxaliplatin ° J9206, J9205 for irinotecan	• Establishing evidence of wild-type *RAS* and confirming previous therapy with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy may require patient chart review • Vectibix® is not indicated for patients with *RAS*-mutant mCRC or for whom *RAS*-mutation in unknown • These patients include those with documented disease progression after previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy • These patients do not include those who are treatment-naïve • HCPCS codes may be used to identify patients who were previously treated with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

Key: CPT = Current Procedural Terminology; FDA = Food and Drug Administration; HCPCS = Healthcare Common Procedure Coding System; ICD-10 = International Classification of Diseases, 10th Revision, Clinical Modification.

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IMPORTANT SAFETY INFORMATION

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 *[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 (e.g., 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®.

Serious cases of keratitis, ulcerative keratitis, and corneal perforation have occurred with Vectibix® use. 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.

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.

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

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AMGEN IS COMMITTED TO HELPING YOUR PATIENTS ACCESS VECTIBIX®

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*Amgen Nurse Navigators are only available to patients that are prescribed certain products. Nurse Navigators are there to support, not replace, your treatment plan and do not provide medical advice or case management services. Patients should always consult their healthcare provider regarding medical decisions or treatment concerns.

†Resources include referrals to independent nonprofit patient assistance programs. Eligibility for resources provided by independent nonprofit patient assistance programs is based on the nonprofits' criteria. Amgen has no control over these programs and provides referrals as a courtesy only.

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§$25 out-of-pocket cost for each dose of Prolia® (denosumab) and EVENITY® (romosozumab-aqqg) through Amgen SupportPlus.

References

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Colon Cancer V.2.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed November 21, 2022. To view the most recent and complete version of the guideline, go to NCCN.org. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Rectal Cancer V.3.2022. © National Comprehensive Cancer Network, Inc. 2022. All rights reserved. Accessed November 29, 2022. To view the most recent and complete version of the guideline, go to NCCN.org.

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