Vectibix® (panitumumab)
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USING YOUR EMR SYSTEM TO IDENTIFY METASTATIC COLORECTAL CANCER PATIENTS WHO MAY BE APPROPRIATE FOR VECTIBIX® (PANITUMUMAB)

The purposes of this resource are as follows:

1. To describe clinical guidelines for Vectibix®, focusing on characteristics of patients who may be appropriate for this treatment.
2. To report clinical data on the benefits of Vectibix®.
3. To provide examples of queries that may be applied to your EMR system to help identify these patients.

This tool should not be used for coding or reimbursement.*

EMR = electronic medical record.
*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.

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.

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

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CLINICAL PRACTICE GUIDELINES

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,†]

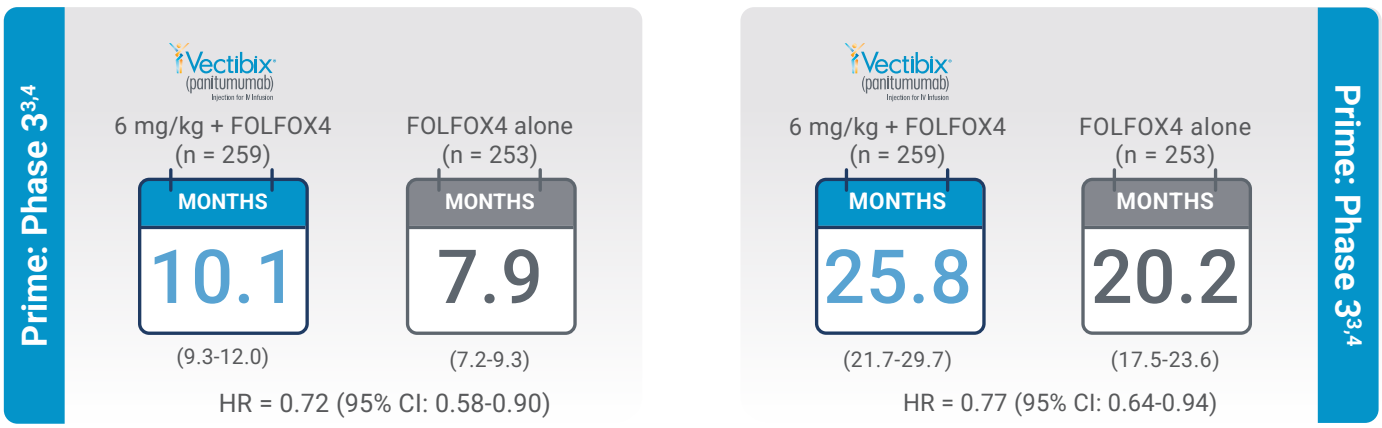
Additionally, per the ASCO Guidelines Recommendation 3.1. Anti–epidermal growth factor receptor (EGFR) therapy plus doublet chemotherapy should be offered as first-line therapy to patients with MSS or pMMR left-sided *RAS* wild-type mCRC (Type: Evidence-based, benefits outweigh harms; Evidence quality: Moderate; Strength of recommendation: Strong).

NCCN = National Comprehensive Cancer Network® (NCCN®).
*Patients with WT RAS / WT BRAF mCRC, and left-sided colon tumors only. 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.

CLINICAL DATA FOR VECTIBIX®

THE EFFICACY OF VECTIBIX® (PANITUMUMAB) AS 1L THERAPY WAS FIRST ESTABLISHED IN PRIME, A PHASE 3 STUDY

Results from the post-hoc analysis of the WT *RAS*‡ subgroup



Early targeted therapy with Vectibix® + FOLFOX4 improved survival in newly diagnosed WT *RAS*‡ mCRC patients[3,4]

Per the Vectibix® Prescribing Information, there are no OS or PFS benefits in patients treated with Vectibix® with *RAS*-mutant mCRC.[3]

PRIME PHASE 3 STUDY DESIGN

PRIME was an open-label, randomized (1:1), multicenter study of Vectibix® Q2W + FOLFOX4 vs FOLFOX4 Q2W alone in treatment of newly diagnosed mCRC patients. Among the study population of 1,183 patients with previously untreated mCRC, 656 were WT *KRAS*§ patients. The extended *RAS* population in the post-hoc analysis consisted of 512 WT *RAS*‡ patients. Of these, 259 received Vectibix® + FOLFOX4 and 253 received FOLFOX4 alone. The primary endpoint was PFS. The key secondary endpoint was OS.[3,4]

‡Defined as wild-type in both *KRAS* and *NRAS*.[5]
§Exon 2 in codons 12 and 13.[5]
1L = first-line; CI = confidence interval; FOLFOX = fluorouracil, leucovorin, and oxaliplatin; HR = hazard ratio; mCRC = metastatic colorectal cancer; OS = overall survival; PFS = progression-free survival; PRIME = Panitumumab Randomized Trial in Combination With Chemotherapy for Metastatic Colorectal Cancer to Determine Efficacy; Q2W = every 2 weeks; WT = wild-type.

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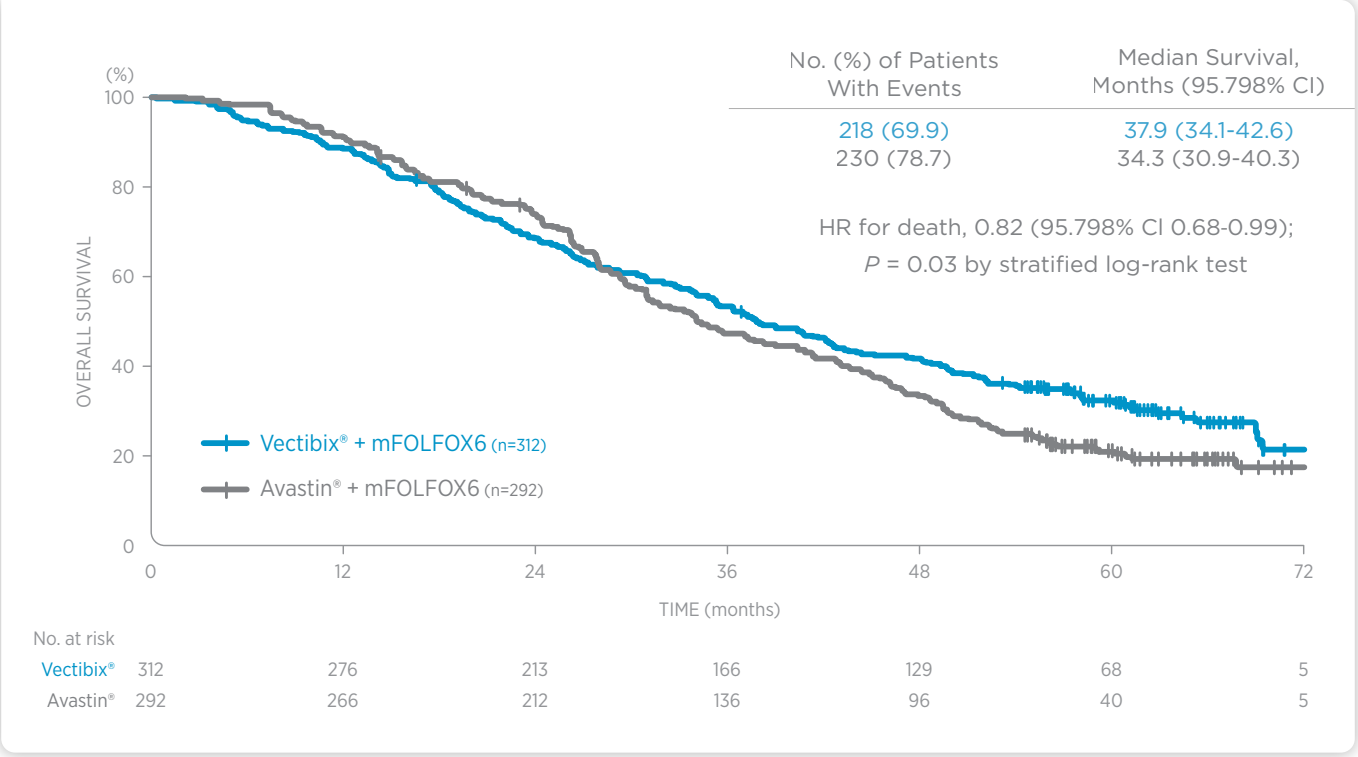
THE PARADIGM STUDY

PARADIGM — a Head-to-Head Study (n=823) Supporting the Efficacy of Vectibix® vs Avastin® in Japanese Patients With WT *RAS** Left-Sided mCRC

A head-to-head, prospective, randomized (1:1), multicenter, Phase 3 study comparing 1L Vectibix® (panitumumab) + mFOLFOX6† vs Avastin® (bevacizumab) + mFOLFOX6† in 802 Japanese patients with WT *RAS** mCRC and left-sided primary tumors. 400 patients were randomized to the Vectibix® + mFOLFOX6† arm and 312 of those patients had left-sided primary tumors; and 402 patients were randomized to Avastin® + mFOLFOX6† and 292 of those patients had left-sided primary tumors. The primary endpoint of the study was OS in the left-sided population and, if results were significant, OS in the overall population. Secondary endpoints included PFS and safety.[5]

PRIMARY ENDPOINT:
Overall Survival in Left-Sided Population



Vectibix® plus mFOLFOX6 provided a survival benefit vs Avastin® plus mFOLFOX6, reinforcing the clinical value of Vectibix® as a first-line treatment in patients with WT *RAS, left-sided metastatic colorectal cancer.**

PFS in left-sided population showed no difference between the two arms of the PARADIGM trial [median survival, months 13.1 (95% CI: 11.6-14.5) for Vectibix® + mFOLFOX6 arm vs 11.9 (95% CI: 11.3-13.5) bevacizumab + mFOLFOX6].[5]

- Patients who underwent curative-intent resection were censored from this analysis once it was confirmed that they did not have progressive disease.[5] Omission of these patients could have impacted the PFS results.
- **Analysis was not powered or adjusted for multiplicity to assess efficacy on this endpoint.**

*Defined as wild-type in both *KRAS* and *NRAS*.[1]

†Until disease progression, unacceptable toxicity, withdrawal of consent or investigator's judgement or curative intent resection.[5]

1L = first line; CI = confidence interval; mFOLFOX6 = modified 5 fluorouracil, leucovorin, oxaliplatin; HR = hazard ratio; *KRAS* = Kirsten rat sarcoma viral oncogene homolog; mCRC = metastatic colorectal cancer; *NRAS* = neuroblastoma *RAS* viral oncogene homolog; OS = overall survival; PARADIGM = panitumumab plus mFOLFOX6 versus Bevacizumab plus mFOLFOX6 as first line treatment in patients with *RAS* wild-type metastatic colorectal cancer; PFS = progression free survival; *RAS* = rat sarcoma viral oncogene homolog; WT = wild-type.

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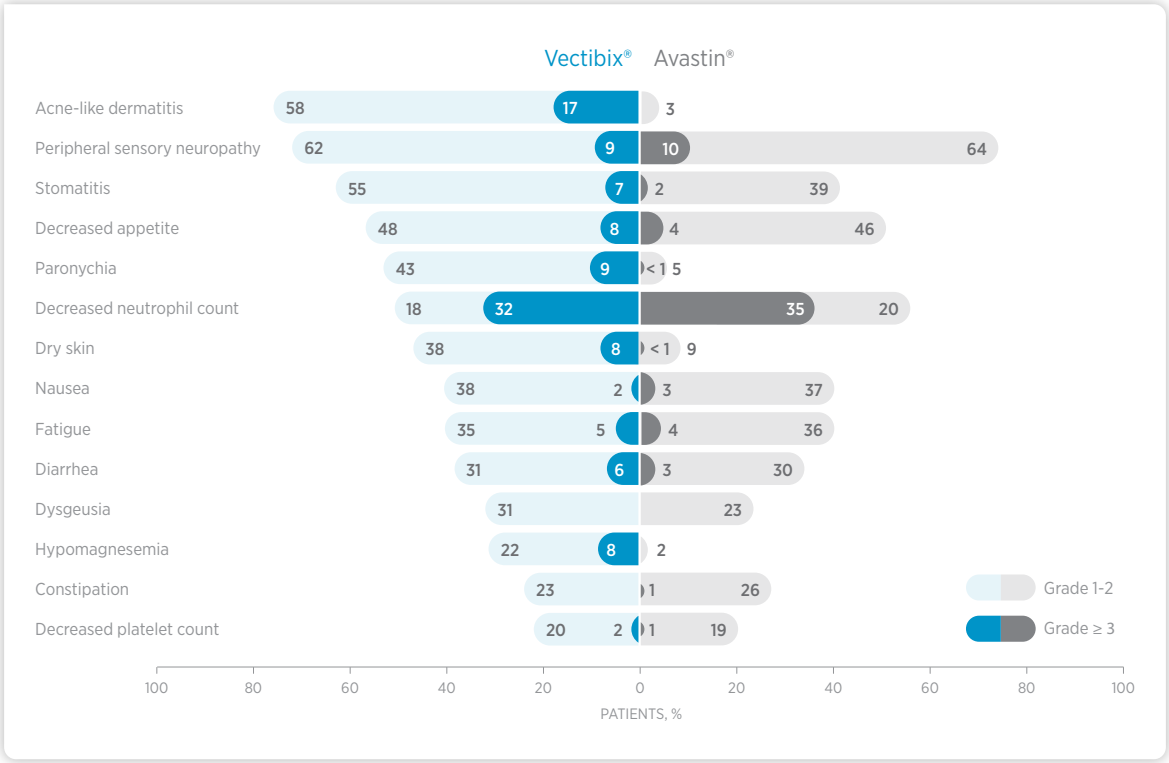
THE PARADIGM STUDY (CONTINUED)

Most Frequent Adverse Events in PARADIGM[5]

Adverse events of any grade in ≥ 20% of patients in either treatment arm.



Dermatological toxicity reactions occurred predominantly in the Vectibix® arm. Prophylactic measures may help reduce the severity of dermatologic toxicities.[6] Examples can be found at VectibixHCP.com.[5]

PARADIGM = Panitumumab and *RAS*. Diagnostically useful Gene Mutation for metastatic colorectal cancer (mCRC).

Important Considerations for the PARADIGM Study

Dosing

- There are two recommended doses for bevacizumab; 5 mg/kg and 10 mg/kg every 2 weeks: PARADIGM studied only the 5 mg/kg dose[5,6]

Study Population

- PARADIGM was conducted in Japanese patients and is not included in US labeling[5]

Outcomes

- Investigators modified the primary endpoint after the study began, from OS in all patients to OS in patients with left-sided tumors[5]
  - This change was based on evidence that the benefit of anti-EGFR antibodies with chemotherapy increases with left-sided tumors[7,8]
  - The statistical analysis plan was modified to require a 2-sided *p*-value of 0.042 as the threshold for statistical significance in the left-sided population[5]
- Panitumumab did not differ from bevacizumab on progression-free survival, and survival curves did not separate before 24 months[5]
- The study was not designed to establish statistical significance on any non-primary endpoint[5]
- There were no differences between panitumumab and bevacizumab in right-sided tumors[5]

EGFR = epidermal growth factor receptor; PARADIGM = Panitumumab and *RAS*, Diagnostically useful Gene Mutation for metastatic colorectal cancer (mCRC).

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CONSIDERATIONS FOR USING EMR TO SEARCH 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 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; *KRAS* = Kirsten rat sarcoma viral oncogene homolog; *NRAS* = Neuroblastoma *RAS* viral oncogene homolog.

*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.

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AS YOU WORK TO IMPLEMENT AN mCRC EMR INITIATIVE, CONSIDER THE FOLLOWING:

1. Who in your practice may find value in taking on and adopting an mCRC EMR initiative?
2. Who is the appropriate individual(s) that can successfully run the list in your EMR system?
3. Once run and potential mCRC patients have been identified, who are the appropriate individuals to share the list with?
4. Now that you've identified your patients, what might patient outreach look like for your clinic? As you are thinking about patient outreach, here might be some things to consider:
   - **a.** Mailings can be created to reach patients with a customized resource (letter, folder, brochure, etc)
   - **b.** Patients with an email address on file can receive an electronic message
   - **c.** Patients enrolled in patient portals can receive patient portal messages
   - **d.** Patients with phone numbers on file can receive a phone message
   - **e.** Selected patients can be managed by a care coordinator or engaged by a nurse or other staff member
   - **f.** A reminder, an alert, or an order can be created in the EMR for selected patients

To learn more about Vectibix® or if you have questions, please reach out to your Vectibix® representative for patient education materials, patient support services, or production information.

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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.
- 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 see Vectibix® full Prescribing Information, including **Boxed WARNING.**

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Personalized support that you and your patients can count on across Amgen therapies.

AMGEN® ACCESS SPECIALISTS

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*Eligibility criteria and program maximums apply. See AmgenSupportPlus.com/copay for full Terms and Conditions.

References

1. Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Colon Cancer V.2.2026. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed June 02, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. **2.** Referenced with permission from the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®) for Rectal Cancer V.2.2026. © National Comprehensive Cancer Network, Inc. 2025. All rights reserved. Accessed June 02, 2026. To view the most recent and complete version of the guideline, go online to NCCN.org. **3.** Vectibix® (panitumumab) prescribing information, Amgen. **4.** Douillard J-Y, Oliner KS, Siena S, et al. *N Engl J Med.* 2013;369:1023-1034. **5.** Watanabe J, Muro K, Shitara K, et al. *JAMA*. 2023;329(15):1271-1282. **6.** Avastin® (bevacizumab) prescribing information, Genentech. **7.** Chen D, Li L, Zhang X, et al. *Medicine (Baltimore).* 2018;97(10):e0097. **8.** Arnold D, Lueza B, Douillard J-Y, et al. *Ann Oncol.* 2017;28(8):1713-1729.

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