

Vectibix® (panitumumab) – Expanded indication

- On June 29, 2017, [Amgen announced](#) the FDA approval of [Vectibix \(panitumumab\)](#) 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 and as monotherapy following disease progression after prior treatment with fluoropyrimidine-, [Eloxatin® \(oxaliplatin\)](#)-, and [irinotecan](#)-containing chemotherapy.
 - Previously, Vectibix was approved for use in patients with wild-type *KRAS* (exon 2 in codons 12 or 13) mCRC.
- Vectibix is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.
- As part of this new indication, the FDA approved the first multigene, next-generation sequencing-based test to identify the *RAS* mutation status of a patient's tumor. This companion diagnostic helps physicians identify patients that are more likely to benefit from treatment with Vectibix.
- The approval of the expanded indication for the treatment of patients with wild-type *RAS* mCRC was based on data from a retrospective analysis of the PRIME study and data from the prospective '0007 study.
- The '0007 study evaluated the efficacy of Vectibix plus best supportive care (BSC) vs. BSC alone in 377 patients with chemorefractory, wild-type *KRAS* mCRC. The primary outcome was overall survival (OS) in patients with wild-type *KRAS* mCRC. Secondary outcome measures included OS, progression free survival (PFS) and overall response rate (ORR) in various subgroups.
 - Patients with wild-type *KRAS* mCRC treated with Vectibix plus BSC achieved a median OS of 10 months vs. 7.4 months for patients treated with BSC alone (HR = 0.73; 95% CI: 0.57, 0.93, p = 0.0096).
 - Patients with wild-type *RAS* mCRC treated with Vectibix plus BSC resulted in a statistically significant improvement in OS of 10 months vs. 6.9 months for patients treated with BSC alone (HR = 0.70; 95% CI: 0.53, 0.93, p = 0.0135).
 - In patients with mutant *RAS* mCRC, no differences in OS or PFS were observed between the treatment arms [OS HR = 0.99 (95% CI: 0.49, 2.00); PFS HR = 1.03 (95% CI: 0.56, 1.90)].
 - The ORR in the wild-type *KRAS* population was 27% (95% CI: 20.8, 33.9) vs. 1.6% (95% CI: 0.3, 4.6), in the Vectibix plus BSC arms vs. BSC alone groups, respectively.
 - The ORR in the wild-type *RAS* population was 31% (95% CI: 23.5, 39.3) vs. 2.3% (95% CI: 0.5, 6.7), in the Vectibix plus BSC arms vs. BSC alone groups, respectively.
- The PRIME study evaluated Vectibix and FOLFOX combination therapy vs. FOLFOX monotherapy in 1,183 adults with untreated mCRC. The primary endpoints were PFS and OS.
 - Vectibix plus FOLFOX extended PFS vs. FOLFOX alone in the wild-type *RAS* subgroup (10.1 months vs. 7.9 months, respectively; HR = 0.72, 95% CI: 0.58, 0.90).
 - The median OS for the Vectibix plus FOLFOX group was 25.8 months vs. 20.2 months in the FOLFOX alone group (HR = 0.77; 95% CI: 0.64, 0.94).
 - There were no OS or PFS benefit in Vectibix-treated patients with mutant *RAS* mCRC.
- Vectibix carries a boxed warning for dermatologic toxicity.

- For all indications, the recommended dose of Vectibix is 6 mg/kg, administered as an intravenous infusion over 60 minutes, every 14 days. For doses above 1,000 mg, administer over 90 minutes.



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