**POLICY:** Oncology (Injectable) – Vectibix Utilization Management Medical Policy
- Vectibix® (panitumumab intravenous infusion – Amgen)

**EFFECTIVE DATE:** 1/1/2020
**LAST REVISION DATE:** 11/19/2025

**COVERAGE CRITERIA FOR:** All UCare Plans

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## OVERVIEW

Vectibix, an epidermal growth factor receptor monoclonal antibody, is indicated for the treatment of:[1]

- 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) in adults as:
  - First-line therapy in combination with FOLFOX (5-fluorouracil [5-FU], leucovorin, oxaliplatin).
  - Monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.
- *KRAS G12C* mutated mCRC in combination with Lumakras® (sotorasib tablets) in adults who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

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

## Guidelines

- **Appendiceal Adenocarcinoma:** Guidelines for appendiceal neoplasms and cancers (version 1.2026 – October 30, 2025) recommend Vectibix as second-line and subsequent therapy for advanced or metastatic *KRAS/NRAS/BRAF* wild-type, in combination with FOLFOX, FOLFIRI (5-FU, leucovorin, irinotecan), CapeOX (capecitabine and oxaliplatin) or as a single agent (category 2A). For advanced or metastatic *BRAF V600E* mutation positive disease, Vectibix in combination with Braftovi® (encorafenib capsules) is recommended for initial, second-line, and subsequent therapy (category 2A). Additionally, NCCN recommends Vectibix as second-line and subsequent therapy for advanced or metastatic disease, in combination with Lumakras or Krazati (adagrasib tablets) for *KRAS G12C* mutation positive tumors (category 2A).
- **Colon Cancer:** Guidelines for colon cancer (version 5.2025 – October 30, 2025) recommend Vectibix as initial therapy for advanced or metastatic *KRAS/NRAS/BRAF* wild-type and left-sided tumors only in combination with FOLFOX, FOLFIRI, or CapeOX regimens in patients who can tolerate intensive therapy (category 2A) or as a single agent in patients who cannot tolerate intensive therapy (category 2B).[2,4] Reference to left-sided only disease refers to a primary tumor that originated in the left side of the colon. Vectibix in combination with Braftovi or Braftovi and FOLFOX is recommended for the initial, second-line and subsequent treatment of advanced or metastatic *BRAF V600E* mutation positive disease (category 2A). The NCCN guidelines recommend Vectibix, for initial, second-line, and subsequent therapy for advanced or metastatic *KRAS G12C* positive tumors, in combination with Lumakras or Krazati.
- **Rectal Cancer:** Guidelines for rectal cancer (version 4.2025 – October 31, 2025) recommend Vectibix as initial, second-line and subsequent therapy for advanced or metastatic

*KRAS/NRAS/BRAF* wild-type, in combination with FOLFOX, FOLFIRI, irinotecan, or CapeOX regimens in patients who can tolerate intensive therapy (category 2A) or as a single agent in patients who cannot tolerate intensive therapy (category 2B).[2,6] Vectibix in combination with Braftovi is recommended for the initial, second-line and subsequent treatment of advanced or metastatic *BRAF V600E* mutation positive disease (category 2A). The NCCN guidelines recommend Vectibix for initial, second-line, and subsequent therapy for advanced or metastatic *KRAS G12C* positive tumors, in combination with Lumakras or Krazati (category 2A).

## POLICY STATEMENT

Prior Authorization is recommended for medical benefit coverage of Vectibix. Approval is recommended for those who meet the **Criteria** and **Dosing** for the listed indications. Extended approvals are allowed if the patient continues to meet the Criteria and Dosing. Requests for doses outside of the established dosing documented in this policy will be considered on a case-by-case basis by a clinician (i.e., Medical Director or Pharmacist). All approvals are provided for the duration noted below. Because of the specialized skills required for evaluation and diagnosis of patients treated with Vectibix, as well as the monitoring required for adverse events and long-term efficacy, approval requires Vectibix to be prescribed by or in consultation with a physician who specializes in the condition being treated.

**Automation:** None.

## RECOMMENDED AUTHORIZATION CRITERIA

Coverage of Vectibix is recommended in those who meet one of the following criteria:

### FDA-Approved Indication

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**1. Colon Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
Note: For rectal cancer, refer to the respective criteria under FDA-approved indications.

- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has advanced or metastatic disease and meets ONE of the following (i, ii or iii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **1.** Tumor or metastases are *KRAS/NRAS/BRAF* wild-type; AND
      Note: The tumor or metastases are *KRAS*, *NRAS*, and *BRAF* mutation negative.
    - **2.** Patient meets ONE of the following [(1) or (2)]:
      1. The primary tumor originated on the left side of the colon; OR
         Note: The primary tumor originated from the splenic flexure to the rectum.
      2. The medication is used as subsequent therapy; OR
  - **ii.** Patient meets BOTH of the following (a and b):
    - **1.** Tumor or metastases are *BRAF V600E* mutation-positive; AND
    - **b)** The medication is used in combination with Braftovi (encorafenib capsules); OR
  - **iii.** Patient meets BOTH of the following (a and b):
    - **a)** Tumor or metastases are *KRAS G12C* mutation positive; AND
    - **b)** The medication is used in combination with Lumakras (sotorasib tablets) or Krazati (adagrasib tablets); AND
- **C)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve up to 6 mg/kg administered by intravenous infusion, given no more frequently than once every 14 days.

**2. Rectal Cancer.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
Note: For colon cancer, refer to the respective criteria under FDA-approved indications.
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has advanced or metastatic disease and meets ONE of the following (i, ii, or iii):
  - **a)** Tumor or metastases are *KRAS/NRAS/BRAF* wild-type; OR
  - **b)** Patient meets BOTH of the following (a and b):
    - **a)** Tumor or metastases are *BRAF V600E* mutation-positive; AND
    - **b)** The medication is used in combination with Braftovi (encorafenib capsules); OR
  - **iii.** Patient meets BOTH of the following (a and b):
    - **1.** Tumor or metastases are *KRAS G12C* mutation positive; AND
    - **2.** The medication is used in combination with Lumakras (sotorasib tablets) or Krazati (adagrasib tablets); AND
- **C)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve up to 6 mg/kg administered by intravenous infusion, given no more frequently than once every 14 days

**Other Uses with Supportive Evidence**

**3. Appendiceal Adenocarcinoma.** Approve for 1 year if the patient meets ALL of the following (A, B, and C):
- **A)** Patient is ≥ 18 years of age; AND
- **B)** Patient has advanced or metastatic disease and meets ONE of the following (i, ii, or iii):
  - **i.** Patient meets BOTH of the following (a and b):
    - **(1)** Tumor or metastases are *KRAS/NRAS/BRAF* wild-type; AND
      Note: The tumor or metastases are *KRAS*, *NRAS*, and *BRAF* mutation negative
    - **b)** The medication is used for subsequent therapy; OR
  - **ii.** Patient meets BOTH of the following (a and b):
    - **a)** Tumor or metastases are *BRAF V600E* mutation-positive; AND
    - **b)** The medication is used in combination with Braftovi (encorafenib capsules); OR
  - **iii.** Patient meets ALL of the following (a, b, and c):
    - **a)** Tumor or metastases are *KRAS G12C* mutation positive; AND
    - **b)** The medication is used for subsequent therapy; AND
    - **c)** The medication is used in combination with Lumakras (sotorasib tablets) or Krazati (adagrasib tablets); AND
- **C)** The medication is prescribed by or in consultation with an oncologist.

**Dosing.** Approve up to 6 mg/kg administered by intravenous infusion, given no more frequently than once every 14 days.

## CONDITIONS NOT RECOMMENDED FOR APPROVAL

Coverage of Vectibix is not recommended in the following situations:

**1.** Coverage is not recommended for circumstances not listed in the Recommended Authorization Criteria. Criteria will be updated as new published data are available.

## REFERENCES

1. Vectibix® intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen; January 2025.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 5.2025 – October 30, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 31, 2025.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 3.2025 – August 26, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 31, 2025.
4. The NCCN Drugs and Biologics Compendium. © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 31, 2025. Search term: panitumumab.
5. The NCCN Appendiceal Neoplasms and Cancer Clinical Practice Guidelines in Oncology (version 1.2026 – October 30, 2025). © 2025 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on October 31, 2025.

## HISTORY

| Type of Revision | Summary of Changes | Review Date |
|---|---|---|
| Annual Revision | **Colon and Rectal Cancer:** Patient is ≥ 18 years of age added as additional requirement. Unresectable added as descriptor to patient has unresectable, advanced, or metastatic disease. | 08/02/2023 |
| Annual Revision | **Colon and Rectal Cancer:** Add new option for approval for patients with unresectable synchronous liver and/or lung metastases. Added new option for approval for patients with unresectable metachronous metastases. Removed criterion that the tumor or metastases are wild-type *BRAF* and criterion that the patient has previously received a chemotherapy regimen for colon or rectal cancer. Removed unresectable from criterion that the patient has advanced or metastatic disease and meets one of the following. Added *BRAF* to criterion that the tumor or metastases are *KRAS/NRAS/BRAF* mutation negative; and added medication is for initial therapy and medication is used in combination with FOLFOX, CapeOX, or FOLFIRI to condition of approval. Added condition of approval for the subsequent treatment of *KRAS/NRAS/BRAF* mutation negative disease. Added condition of approval for *BRAF V600E* mutation positive disease. Added condition of approval for *KRAS G12C* mutation positive disease.<br>**Appendiceal Adenocarcinoma:** Added new condition of approval. | 08/07/2024 |
| UCare P&T Review | Policy reviewed and approved by UCare P&T committee. Annual review process | 09/16/2024 |
| Early Annual Revision | **Colon and Rectal Cancer:** As a single agent added to the requirement that the medication is used as a single agent or in combination with FOLFOX, CapeOX, or FOLFIRI. Removed requirement that the medication is used for subsequent treatment. This is subsequent therapy following the initial diagnosis of Colon or rectal cancer added as a Note. Added synchronous metastases are metastases that are diagnosed at the same time as or within a few months of the initial diagnosis of colon or rectal cancer as a Note. Added metachronous metastases are metastases that are diagnosed months to years after the initial diagnosis of colon or rectal cancer.<br>**Appendiceal Adenocarcinoma:** Medication is used for subsequent treatment removed as a requirement. | 02/26/2025 |
| UCare P&T Review | Policy reviewed and approved by UCare P&T committee. Annual review process | 09/15/2025 |
| Early Annual Revision | **Colon Cancer:** This indication was changed to as listed (previously was Colon and Rectal Cancer). A note was added stating: "For rectal cancer, refer to the respective criteria under FDA-approved indications". The following options of approval along with their associated notes were removed: The patient has unresectable synchronous liver and/or lung metastases; patient has unresectable metachronous metastases. For a patient with advanced or metastatic disease, the following requirements were removed: The medication is used for initial treatment; the medication is used as a single agent or in combination with irinotecan, FOLFOX, CapeOX, or FOLFIRI. In the option of approval that the tumor or metastases are *KRAS G12C* mutation positive, the requirement that the medication is used for subsequent therapy was removed.<br>**Rectal Cancer:** This new condition of approval was added. | 11/19/2025 |

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| | **Appendiceal Adenocarcinoma:** Options for approval were added to include cases where tumor or metastases are *KRAS/NRAS/BRAF* wild-type and the medication is used for subsequent therapy. | |