POLICY: Oncology (Injectable) – Vectibix Utilization Management Medical Policy

- Vectibix® (panitumumab intravenous infusion – Amgen)

EFFECTIVE DATE: 1/1/2020
LAST REVISION DATE: 09/16/2024

COVERAGE CRITERIA FOR: All UCare Plans

OVERVIEW

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

- 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.

Limitation of use: Vectibix is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.

Guidelines

The National Comprehensive Cancer Network (NCCN) **Colon Cancer** guidelines (version 4.2024 – July 3, 2024) recommend Vectibix as primary therapy for unresectable, advanced, or metastatic *KRAS/NRAS/BRAF* wild-type gene and left-sided tumors only in combination with irinotecan, FOLFOX, FOLFIRI (5-FU, leucovorin, irinotecan), or CapeOX (capecitabine and oxaliplatin) regimens in patients who can tolerate intensive therapy or as a single agent in patients who cannot tolerate intensive therapy.[2,4] Reference to left-sided only disease refers to a primary tumor that originated in the left side of the colon. For the initial treatment of unresectable metachronous metastases, NCCN recommends Vectibix in combination with irinotecan or FOLFIRI for *KRAS/NRAS/BRAF* wild-type; in combination with Braftovi for *BRAF V600E* mutation positive disease; or in combination with Lumakras (sotorasib tablets) or Krazati (adagrasib tablets) for *KRAS G12C* mutation positive tumors. Therapies recommended after first progression vary depending on the initial treatment regimen (i.e., 5-FU/leucovorin-based or capecitabine-based therapy) that was used. The NCCN guidelines recommend Vectibix, in combination with irinotecan, FOLFOX, CapeOX, or FOLFIRI for the subsequent treatment of *KRAS/NRAS/BRAF* wild-type tumors; in combination with Braftovi® (encorafenib capsules) for the subsequent treatment of *BRAF V600E* mutation positive disease; or in combination with Lumakras or Krazati for *KRAS G12C* positive tumors. The NCCN **Rectal Cancer** guidelines (version 3.2024 – July 3, 2024) make the same recommendations for Vectibix for the treatment of rectal cancer.[3,4]

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

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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 and Rectal Cancer.** 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 meets ONE of the following (i, ii, or iii):
     - **i.** Patient has unresectable synchronous liver and/or lung metastases and meets ALL of the following (a, b, c, and d):
       - **a)** Metastases are *KRAS/NRAS/BRAF* wild-type; AND
         Note: The metastases are *KRAS/NRAS/BRAF* mutation negative.
       - **b)** The primary tumor originated on the left side of the colon; AND
         Note: Primary tumor originated from the splenic flexure to the rectum.
       - **c)** Medication is used for primary treatment; AND
       - **d)** Medication is used in combination with FOLFOX or FOLFIRI; OR
         Note: FOLFOX includes 5-fluorouracil, leucovorin, and oxaliplatin and FOLFIRI includes fluorouracil, leucovorin, and irinotecan.
     - **ii.** Patient has unresectable metachronous metastases and meets ONE of the following (a, b, or c):
       - **a)** Patient meets ALL of the following [(1), (2), and (3)]:
         - **1.** Metastases are *KRAS/NRAS/BRAF* wild-type; AND
           Note: The metastases are *KRAS/NRAS/BRAF* mutation negative.
         - **2.** Medication is used for initial treatment; AND
         - **3.** Medication is used in combination with irinotecan or FOLFIRI; OR
           Note: FOLFIRI includes fluorouracil, leucovorin, and irinotecan.
       - **b)** Patient meets ALL of the following [(1), (2), and (3)]:
         - **1.** Metastases are *BRAF V600E* mutation positive; AND
         - **2.** Medication is used for initial treatment; AND
         - **3.** Medication is used in combination with Braftovi (encorafenib capsules); OR
       - **c)** Patient meets ALL of the following [(1), (2), and (3)]:
         - **1.** Metastases are *KRAS G12C* mutation positive; AND
         - **2.** Medication is used for initial treatment; AND
         - **3.** Medication is used in combination with Lumakras (sotorasib tablets) or Krazati (adagrasib tablets); OR
     - **iii.** Patient has advanced or metastatic disease and meets ONE of the following (a, b, c, or d):
       - **a)** Patient meets ALL of the following [(1), (2), (3), and (4)]:
         - **1.** Tumor or metastases are *KRAS/NRAS/BRAF* wild-type; AND
           Note: The tumor or metastases are *KRAS/NRAS/BRAF* mutation negative.
         - **2.** The primary tumor originated on the left side of the colon; AND
           Note: Primary tumor originated from the splenic flexure to the rectum.
         - **3.** Medication is used for initial treatment; AND
         - **4.** Medication is used in combination with FOLFOX, CapeOX, or FOLFIRI; OR

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Note: FOLFOX includes 5-fluorouracil; leucovorin, and oxaliplatin; CapeOX included capecitabine and oxaliplatin; and FOLFIRI includes 5-fluorouracil, leucovorin, and irinotecan.

b) Patient meets ALL of the following [(1), (2), and (3)]:
  1. Tumor or metastases are *KRAS/NRAS/BRAF* wild-type; AND
  Note: The tumor or metastases are *KRAS/NRAS/BRAF* mutation negative.
  2. Medication is used for subsequent treatment; AND
  3. Medication is used as a single agent or in combination with irinotecan, FOLFOX, CapeOX, or FOLFIRI; OR
  Note: FOLFOX includes 5-fluorouracil, leucovorin, and oxaliplatin; CapeOX included capecitabine and oxaliplatin; and FOLFIRI includes 5-fluorouracil, leucovorin, and irinotecan.

c) Patient meets ALL of the following [(1), (2), and (3)]:
  1. Tumor or metastases are *BRAF V600E* mutation-positive; AND
  2. Medication is used for subsequent treatment; AND
  3. Medication is used in combination with Braftovi; OR

d) Patient meets ALL of the following [(1), (2), and (3)]:
  1. Tumor or metastases are *KRAS G12C* mutation positive; AND
  2. Medication is used for subsequent therapy; AND
  3. Medication is used in combination with Lumkras or Krazati; 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

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2. 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 or ii):
  i. Patient meets ALL of the following (a, b, and c):
    a) Tumor or metastases are *BRAF V600E* mutation-positive; AND
    b) Medication is used for subsequent treatment; AND
    c) Medication is used in combination with Braftovi (encorafenib capsules); OR
  ii. Patient meets ALL of the following (a, b, and c):
    a) Tumor or metastases are *KRAS G12C* mutation positive; AND
    b) Medication is used for subsequent therapy; AND
    c) 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:

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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; August 2021.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (version 4.2024 – July 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 31, 2024.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (version 3.2024 – July 3, 2024). © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 31, 2024.
4. The NCCN Drugs and Biologics Compendium. © 2024 National Comprehensive Cancer Network. Available at: http://www.nccn.org. Accessed on July 31, 2024. Search term: panitumumab.

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. **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

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