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5.21.085

Section:	Prescription Drugs	**Effective Date:**	April 1, 2025
Subsection:	Antineoplastic Agents	**Original Policy Date:**	September 23, 2016
Subject:	Vectibix	**Page:**	1 of 5

Last Review Date: March 7, 2025

Vectibix

Description

Vectibix (panitumumab)

Background
Vectibix is a medication used to treat patients with metastatic colorectal cancer who express the wild-type *KRAS* gene or *KRAS* G12C mutation. Metastatic colorectal cancer is an advanced form of cancer affecting the colon or rectum that has begun spreading to other parts of the body. Epidermal growth factor receptor (EGFR) is a protein involved in the growth and spread of cancer cells. Vectibix competitively blocks this receptor and prevents the activation of kinases, resulting in inhibition of cell growth and induction of cell death (1).

Regulatory Status
FDA-approved indications: Vectibix (panitumumab) is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of: (1)

- 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.
- *KRAS* G12C-mutated Metastatic Colorectal Cancer (mCRC)
  - In combination with sotorasib, for the treatment of adult patients with *KRAS* G12C-mutated mCRC, as determined by an FDA-approved test, who have

received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy.

Limitations of Use: (1)
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.

Off-Label Uses: (2-3)

1. Colorectal Cancer Stage IV – cancer has spread to distant parts of the body
    a. First progression
    b. Second progression
    c. Neoadjuvant therapy
    d. Adjuvant / postoperative, unresectable, or palliative therapy

Vectibix carries a boxed warning for dermatologic toxicity. The reported incidence of dermatologic toxicities was 90%, while 15% of these patients experienced severe (NCI-CTC grade 3 and higher) toxicities in those who received monotherapy. Withhold or discontinue Vectibix for dermatologic or soft tissue toxicity associated with severe or life-threatening inflammatory or infectious complications (1).

Safety and effectiveness of Vectibix in pediatric patients less than 18 years of age have not been established (1).

Related policies
Erbitux

Policy

This policy statement applies to clinical review performed for pre-service (Prior Approval, Precertification, Advanced Benefit Determination, etc.) and/or post-service claims.

Vectibix may be considered **medically necessary** if the conditions indicated below are met.

Vectibix may be considered **investigational** for all other indications.

Prior-Approval Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic colorectal cancer with **ONE** of the following:

a. *KRAS/NRAS* wild-type gene expression as determined by FDA-approved tests
b. Presence of KRAS G12C mutation as determined by an FDA-approved test **AND** used in combination with Lumakras (sotorasib)

AND the following:

a. Prescriber agrees to monitor for dermatologic and soft tissue toxicities and discontinue if severe complications occur

Prior – Approval *Renewal* Requirements

Age 18 years of age or older

Diagnosis

Patient must have the following:

Metastatic colorectal cancer

AND ALL of the following:

a. **NO** disease progression or unacceptable toxicity
b. Prescriber agrees to monitor for dermatologic and soft tissue toxicities and discontinue if severe complications occur

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Prior – Approval *Renewal* Limits

Same as above

Rationale

Summary

Vectibix (panitumumab) is indicated for the treatment of metastatic colorectal cancer. Vectibix should be used for wild-type *RAS* or *KRAS* G12C-mutations. In addition, there is an evidence base to support the off-label use of Vectibix in combination with FOLFIRI or irinotecan, or as monotherapy in individuals who cannot tolerate intensive therapy to treat unresectable advanced or metastatic colorectal cancer expressing *KRAS/NRAS* mutations. Safety and effectiveness of Vectibix in pediatric patients less than 18 years of age have not been established (1-2).

Prior authorization is required to ensure the safe, clinically appropriate, and cost-effective use of Vectibix while maintaining optimal therapeutic outcomes.

References

1. Vectibix [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; January 2025.
2. NCCN Drugs & Biologics Compendium® Panitumumab 2025. National Comprehensive Cancer Network, Inc. Accessed on February 3, 2025.
3. NCCN Clinical Practice Guidelines in Oncology® Colon Cancer (Version 6.2024). National Comprehensive Cancer Network, Inc. January 2025. Accessed on February 3, 2025.

Policy History

Date	Action
September 2016	Addition to PA
December 2016	Annual review

June 2018	Annual editorial review and reference update Update in criteria by streamlining to metastatic colorectal cancer *KRAS/NRAS* wild-type gene expression as determined by FDA-approved tests, removal of other qualifiers for use for colon cancer.
June 2019	Annual review and reference update
June 2020	Annual review and reference update
December 2021	Annual review and reference update
December 2022	Annual review and reference update. Changed policy number to 5.21.085
December 2023	Annual review and reference update
December 2024	Annual review and reference update
January 2025	Per PI update, added indication of KRAS G12C-mutated metastatic colorectal cancer
March 2025	Annual review and reference update

Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on March 7, 2025 and is effective on April 1, 2025.