Vectibix (panitumumab)

Background
Vectibix is a medication used to treat patients with advanced or metastatic colorectal cancer who express the wild-type KRAS gene. 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 wild-type KRAS (exon 2) metastatic colorectal cancer (mCRC) as determined by an FDA-approved test for this use: (1)

1. In combination with FOLFOX for first-line treatment.
2. As monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy.

Limitation of Use: (1)
Vectibix is not indicated for the treatment of patients with RAS-mutant mCRC or 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 (1).

Safety and effectiveness of Vectibix in pediatric patients 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 for the treatment of patients age 18 years
and older with metastatic colorectal cancer and when the conditions indicated below are met.

Vectibix is considered investigational in patients less than 18 years of age and for all other
indications.

Prior-Approval Requirements

Age

18 years of age or older

Diagnosis

Patient must have the following:

Metastatic colorectal cancer
   a. KRAS/NRAS wild-type gene expression as determined by FDA-approved
tests

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

b. NO disease progression or unacceptable toxicity

Policy Guidelines

Pre - PA Allowance

None

Prior - Approval Limits

Duration 12 months

Summary

Vectibix (panitumumab) is medically necessary for the treatment of metastatic colorectal cancer. Vectibix should be used as first-line therapy in combination with FOLFOX regimen for KRAS expressing tumors, or as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing regimens. 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 (1-2).

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

References


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<td>December 2016</td>
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<td>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.</td>
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Keywords

This policy was approved by the FEP® Pharmacy and Medical Policy Committee on June 20, 2019 and is effective on July 1, 2019.