Panitumumab (Vectibix®)

Prior Authorization Drug Coverage Policy

Effective Date: 9/1/2020
Revision Date: n/a
Review Date: 10/4/2021
Lines of Business: Commercial
Policy type: Prior Authorization

This Drug Coverage Policy provides parameters for the coverage of Panitumumab (Vectibix®). Consideration of medically necessary indications are based upon U.S. Food and Drug Administration (FDA) indications, recommended uses within the Centers of Medicare & Medicaid Services (CMS) five recognized compendia, including the National Comprehensive Cancer Network (NCCN) Drugs & Biologics Compendium (Categories 1 and 2A), and peer-reviewed scientific literature eligible for coverage according to the CMS, Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 titled, "Off-Label Use of Anti-Cancer Drugs and Biologics." This policy evaluates whether the drug therapy is proven to be effective based on published evidence-based medicine.

Drug Description[1]

Panitumumab binds specifically to EGFR (epidermal growth factor receptor) on both normal and tumor cells, and competitively inhibits the binding of ligands for EGFR. Nonclinical studies show that binding of panitumumab to the EGFR prevents ligand-induced receptor autophosphorylation and activation of receptor-associated kinases, resulting in inhibition of cell growth, induction of apoptosis, decreased proinflammatory cytokine and vascular growth factor production, and internalization of the EGFR. In vitro assays and in vivo animal studies demonstrate that panitumumab inhibits the growth and survival of selected human tumor cell lines expressing EGFR.

Indications

FDA Indications[1]

Panitumumab is FDA indicated for the following:

- Treatment of 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 (5-FU, leucovorin, oxaliplatin) as first-line treatment OR
    - As monotherapy following disease progression after prior treatment with 5-FU, oxaliplatin, and irinotecan-containing chemotherapy.

Recommended dosage: 6 mg/kg IV every 14 days.

NCCN Compendium Supported Indications[2]

- Colon cancer.
- Rectal cancer.

Recommended dosage: 6 mg/kg IV every 14 days.

Coverage Determinations[1-2]

Panitumumab will require prior authorization. This agent is considered medically necessary for the following oncology indications if all criteria below are met:

Metastatic colorectal cancer

1) The member has a diagnosis of colorectal cancer with unresectable metachronous metastases **AND**
    - Panitumumab is being used as primary treatment for KRAS/NRAS/BRAF wild-type gene and left-sided tumors (left-sided tumors applies to colon cancer only) **AND**
    - The member has received previous adjuvant FOLFOX or CapeOX (capecitabine and oxaliplatin) within the past 12 months **AND**
    - Panitumumab is being used in combination with irinotecan **OR** in combination with FOLFIRI (5-FU, leucovorin, and irinotecan).
2) The member has a diagnosis of colorectal cancer with unresectable metachronous metastases **AND**
    - The member is BRAF V600E mutation positive **AND**
    - Panitumumab is being used as primary treatment in combination with encorafenib **AND**
    - The member has received previous adjuvant FOLFOX or CapeOX within the past 12 months.
3) The member has a diagnosis of colon cancer **AND**
    - The member has KRAS/NRAS/BRAF wild-type gene and a left-sided tumor **AND**
    - Panitumumab is being used in combination with FOLFOX or FOLFIRI in patients appropriate for intensive therapy:
        - As primary treatment for locally unresectable or medically inoperable disease **OR**
        - For unresectable synchronous liver and/or lung metastases that remain unresectable after primary systemic therapy **OR**
        - As primary treatment for synchronous abdominal/peritoneal metastases that are non-obstructing, or following local therapy for patients with existing or imminent obstruction **OR**
        - For synchronous unresectable metastases of other sites **OR**
        - As primary treatment for unresectable metachronous metastases in patients who have not received previous adjuvant FOLFOX or CapeOX within the past 12 months, who have received previous 5-FU/leucovorin (5-

FU/LV) or capecitabine therapy, or who have not received any previous chemotherapy **OR**
- For unresectable metachronous metastases that remain unresectable after primary treatment **OR**
- The member has progressed on non-intensive therapy, except if received previous 5-FU, with improvement in functional status.

4) The member has a diagnosis of colorectal cancer **AND**
   - Panitumumab is being used as subsequent therapy in combination with encorafenib for progression of advanced or metastatic disease (BRAF V600E mutation positive) in patients previously treated with:
     - Oxaliplatin-based therapy without irinotecan **OR**
     - Irinotecan-based therapy without oxaliplatin **OR**
     - Oxaliplatin and irinotecan **OR**
     - A fluoropyrimidine without irinotecan or oxaliplatin **OR**
     - A fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX or CapeOX with or without bevacizumab.
5) The member has a diagnosis of colorectal cancer **AND**
   - Panitumumab is being used as subsequent therapy for progression of advanced or metastatic disease (KRAS/NRAS/BRAF wild-type only) not previously treated with cetuximab or panitumumab:
     - In combination with irinotecan, FOLFIRI, or as a single agent for patients who cannot tolerate irinotecan, if previously treated with oxaliplatin-based therapy without irinotecan **OR**
     - In combination with irinotecan, FOLFOX, or as a single agent for patients who cannot tolerate irinotecan, if previously treated with irinotecan-based therapy without oxaliplatin **OR**
     - In combination with irinotecan or as a single agent for patients who cannot tolerate irinotecan if previously treated with oxaliplatin and irinotecan **OR**
     - In combination with irinotecan or as a single agent for patients who cannot tolerate irinotecan if previously treated with a fluoropyrimidine without irinotecan or oxaliplatin followed by FOLFOX or CapeOX with or without bevacizumab.
6) The member has a diagnosis of colorectal cancer **AND**
   - Panitumumab is being used as primary treatment for unresectable synchronous liver and/or lung metastases (KRAS/NRAS/BRAF wild-type gene and left-sided tumors only) in combination with:
     - FOLFOX **OR**
     - FOLFIRI.
7) The member has a diagnosis of rectal cancer **AND**
   - Panitumumab is being used for KRAS/NRAS/BRAF wild-type gene tumors in combination with FOLFOX or FOLFIRI in patients appropriate for intensive therapy:
     - As primary treatment for T3, N Any; T1-2, N1-2; T4, N Any; or locally unresectable or medically inoperable disease if resection is contraindicated following neoadjuvant therapy **OR**

- For synchronous liver only and/or lung only metastases that are unresectable or medically inoperable and remain unresectable (with no progression of primary tumor) after primary systemic therapy **OR**
- Following palliative radiation therapy (RT) or chemo/RT for synchronous liver only and/or lung only metastases that are unresectable or medically inoperable and remain unresectable (with progression of primary tumor) after primary systemic therapy **OR**
- As primary treatment for synchronous abdominal/peritoneal metastases that are non-obstructing, or following local therapy for patients with existing or imminent obstruction **OR**
- As primary treatment for synchronous unresectable metastases of other sites **OR**
- As primary treatment for unresectable metachronous metastases in patients who have not received previous adjuvant FOLFOX or CapeOX within the past 12 months, who have received previous 5-FU/LV or capecitabine therapy, or who have not received any previous chemotherapy **OR**
- For unresectable metachronous metastases that remain unresectable after primary treatment **OR**
- The member has progressed on non-intensive therapy, except if received previous fluoropyrimidine, with improvement in functional status.

Recommended dosage: 6 mg/kg IV every 14 days.

All indications:

- Panitumumab will be approved through clinical review up to a 12-month duration.

Coverage Limitations

Treatment with panitumumab is not considered medically necessary for members with the following concomitant conditions:

- Treatment of patients with RAS-mutant mCRC or for whom RAS mutation status is unknown.
- The member has had disease progression on panitumumab or cetuximab.
- Panitumumab may not be used in conjunction with a bevacizumab product.
- Indications not supported by NCCN category 2A or higher recommendations may not be considered medically necessary

Contraindications/Warnings/Precautions[1]

- There are no contraindications listed in the US manufacturer's labeling.
- Warnings/precautions:
    - Dermatologic toxicity [**Boxed warning**]
    - Diarrhea

- Electrolyte depletion
- Infusion reactions
- Pulmonary toxicity (fibrosis and interstitial lung disease)
- Ocular toxicities
- Embryo-fetal toxicity

For specific recommendations on contraindications, warnings and precautions, patient monitoring, and on dose adjustments and discontinuation, please refer to the current prescribing information.

Billing

- Description: injection, panitumumab, 10 mg
  - HCPCS: J9303

Disclaimer

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References

1. Vectibix [package insert]. Amgen, Inc., Thousand Oaks, CA. Available at: https://www.pi.amgen.com/~/media/amgen/repositorysites/pi-amgen-com/vectibix/vectibix_pi.ashx
2. Panitumumab. NCCN Drugs & Biologics Compendium. Available at https://www.nccn.org/professionals/drug_compendium/content/