VENTURA COUNTY
HEALTH CARE PLAN

UTILIZATION REVIEW MEDICAL POLICY

POLICY: Oncology (Injectable) – Vectibix Utilization Review Medical Policy
- Vectibix® (panitumumab solution for intravenous infusion – Amgen Inc.)

REVIEW DATE: 07/22/2020

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 a) first-line therapy in combination with FOLFOX (5-fluorouracil [5-FU], leucovorin, oxaliplatin) or b) monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy.[1] It is a limitation of use that Vectibix is not indicated for the treatment of patients with *RAS*-mutant mCRC or for whom *RAS* mutation status is unknown.

Guidelines

Colon Cancer

The National Comprehensive Cancer Network (NCCN) colon cancer guidelines (version 4.2020 – June 15, 2020) 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 FOLFOXIRI (5-FU, leucovorin, oxaliplatin, irinotecan) 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 and only refers to use of Vectibix as first-line therapy for metastatic disease. 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, or FOLFIRI for the subsequent treatment of *KRAS/NRAS/BRAF* wild-type tumors; or in combination with Braftovi (encorafenib capsules) for the subsequent treatment of *BRAF V600E* positive disease. The NCCN rectal cancer guidelines (version 6.2020 – June 25, 2020) 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 indication(s). 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.

RECOMMENDED AUTHORIZATION CRITERIA

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

FDA-Approved Indication

1. **Colon and Rectal Cancer.** Approve for 1 year if the patient meets the following criteria (A, B, C, D, and E):
   - **A)** Patient has advanced or metastatic disease; AND
   - **B)** Patient's tumor or metastases are wild-type *RAS* (*KRAS* wild-type and/or *NRAS* wild-type) [that is, the tumor or metastases are *KRAS* and/or *NRAS* mutation negative]; AND
   - **C)** If Vectibix is being used for first-line treatment, the primary tumor originated on the left side of the colon (from splenic flexure to rectum); AND
   - **D)** Patient meets ONE of the following criteria (i or ii):
     - **i.** Patient's tumor or metastases are wild-type *BRAF* (that is, the tumor or metastases are *BRAF V600E* mutation-negative); OR
     - **ii.** Patient's tumor or metastases are *BRAF V600E* mutation-positive and the patient meets the following (a and b):
       - **a)** Patient has previously received a chemotherapy regimen for colon or rectal cancer; AND
         Note: Examples of chemotherapy regimens include a fluoropyrimidine such as 5-fluorouracil (5-FU), capecitabine, oxaliplatin, irinotecan, or an adjunctive chemotherapy regimen such as FOLFOX (5-FU, leucovorin, and oxaliplatin) or CapeOX (capecitabine and oxaliplatin).
       - **b)** Vectibix is prescribed in combination with Braftovi (encorafenib capsules).
   - **E)** Vectibix is prescribed by or in consultation with an oncologist.

   Dosing. Approve the following dosing regimen: Each individual dose must not exceed 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® injection for intravenous infusion [prescribing information]. Thousand Oaks, CA: Amgen Inc; June 2017.
2. The NCCN Colon Cancer Clinical Practice Guidelines in Oncology (Version 4.2020 – June 15, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 16, 2020.
3. The NCCN Rectal Cancer Clinical Practice Guidelines in Oncology (Version 6.2020 – June 25, 2020). © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 16, 2020.
4. The NCCN Drugs and Biologics Compendium. © 2020 National Comprehensive Cancer Network, Inc. Available at: http://www.nccn.org. Accessed on July 15, 2020. Search term: panitumumab.

HISTORY

Type of Revision	Summary of Changes	Review Date
Annual	Colorectal cancer criteria updated to include: Vectibix in combination with irinotecan, or irinotecan plus vemurafenib (BRAF V600E mutation positive). Removed Patient has been Started on Vectibix criteria.	08/08/2018
Annual	Removed Initial Approval/Extended Approval, Duration of Therapy and Labs/Diagnostics sections.	07/24/2019

	Increased approval duration to 1 year. Revised colon and rectal cancer criteria E to include the management of patients with *BRAF V600E* mutation-positive and mutation–negative disease. Removed Other Cancer Indications section. Removed Waste Management section. Revised Conditions not Recommended for Approval section.	
Annual revision	Revised *BRAF V600E* mutation-positive disease combination therapy criteria to only include Vectibix in combination with Braftovi (encorafenib capsules).	07/22/2020