Reference number(s)
2035-A

SPECIALTY GUIDELINE MANAGEMENT

VECTIBIX (panitumumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications
Vectibix is indicated for the treatment of patients with 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):
1. As first-line therapy in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin).
2. As 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.

B. Compendial Use
Colorectal cancer

All other indications are considered experimental/investigational and not medically necessary.

II. DOCUMENTATION

Submission of the following information is necessary to initiate the prior authorization review:
A. Documentation of *RAS* wild-type status or KRAS G12C mutation, where applicable.
B. Documentation of *BRAF* mutation status, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

Colorectal Cancer (CRC)
Authorization of 6 months may be granted for the treatment of colorectal cancer, including appendiceal adenocarcinoma and anal adenocarcinoma, for unresectable/inoperable, advanced, or metastatic disease and the member has not previously experienced clinical failure on cetuximab when either of the following criteria are met:
1. The member meets all of the following criteria:
   i. The *RAS (KRAS* and *NRAS)* mutation status is negative (wild-type)
   ii. If the tumor is positive for BRAF V600E mutation, the requested medication will be used in combination with encorafenib (Braftovi)
   iii. For first-line treatment of colon cancer, the tumor is left-sided only, or
2. The member meets all of the following criteria:
   i. The disease is KRAS G12C mutation positive

ii. The requested medication will be used in combination with sotorasib (Lumakras) or adagrasib (Krazati)
iii. The member previously received treatment with chemotherapy

IV. CONTINUATION OF THERAPY

Authorization of 6 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Section III when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

V. REFERENCES

1. Vectibix [package insert]. Thousand Oaks, CA: Amgen Inc.; August 2021.
2. The NCCN Drugs & Biologics Compendium® © 2024 National Comprehensive Cancer Network, Inc. http://www.nccn.org. Accessed February 6, 2024.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer. Version 1.2024. Accessed February 6, 2024. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma. Version 3.2023. Accessed September 22, 2023. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf