Reference number(s)
6299-A

STANDARD MEDICARE PART B 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 Uses

1. Colorectal cancer
2. Advanced non-small cell lung cancer

All other indications will be assessed on an individual basis. Submissions for indications other than those enumerated in this policy should be accompanied by supporting evidence from Medicare approved compendia.

II. DOCUMENTATION

The following documentation must be available, upon request:

A. Documentation of *RAS* wild-type status or KRAS G12C mutation, where applicable.
B. Documentation of *BRAF* mutation status, where applicable.
C. Documentation of epidermal growth factor receptor (EGFR) expression, where applicable.

III. CRITERIA FOR INITIAL APPROVAL

A. **Colorectal Cancer (CRC)**

Authorization of 12 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:

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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

B. Non-Small Cell Lung Cancer
Authorization of 12 months may be granted for treatment of advanced non-small cell lung cancer with EGFR expressing tumors when requested medication is used in combination with paclitaxel and carboplatin.

IV. CONTINUATION OF THERAPY

All members (including new members) requesting authorization for continuation of therapy must be currently receiving therapy with the requested agent.

Authorization for 12 months may be granted when all of the following criteria are met:
A. The member is currently receiving therapy with Vectibix.
B. Vectibix is being used to treat an indication enumerated in Section III.
C. The member is receiving benefit from therapy. Benefit is defined as:
   i. No evidence of unacceptable toxicity while on the current regimen and
   ii. No evidence of disease progression while on the current regimen.

V. SUMMARY OF EVIDENCE

The contents of this policy were created after examining the following resources:
1. The prescribing information for Vectibix.
2. The available compendium
   a. National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium
   b. Micromedex DrugDex
   c. American Hospital Formulary Service- Drug Information (AHFS-DI)
   d. Lexi-Drugs
   e. Clinical Pharmacology
3. NCCN Guideline: Colon cancer
4. NCCN Guideline: Rectal cancer
5. NCCN Guideline: Anal carcinoma

After reviewing the information in the above resources, the FDA-approved indications listed in the prescribing information for Vectibix are covered in addition to the following:
1. Colorectal cancer
2. Advanced non-small cell lung cancer

VI. EXPLANATION OF RATIONALE

Support for FDA-approved indications can be found in the manufacturer's prescribing information.

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Support for using Vectibix to treat colorectal cancer can be found in the NCCN Drugs and Biologics Compendium. Use of information in the NCCN Drugs and Biologics Compendium for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

Support for using Vectibix to treat advanced non-small cell lung cancer can be found in the Micromedex DrugDex database. Use of information in the DrugDex database for off-label use of drugs and biologicals in an anti-cancer chemotherapeutic regimen is supported by the Medicare Benefit Policy Manual, Chapter 15, section 50.4.5 (Off-Label Use of Drugs and Biologicals in an Anti-Cancer Chemotherapeutic Regimen).

VII. 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 14, 2024.
3. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Colon Cancer. Version 1.2024. Accessed February 14, 2024. https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf
4. NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines): Anal Carcinoma. Version 1.2024. Accessed February 14, 2024. https://www.nccn.org/professionals/physician_gls/pdf/anal.pdf
5. Micromedex Solutions [database online]. Truven Health Analytics, Greenwood Village, CO. Available at: http://www.micromedexsolutions.com. Accessed February 14, 2024.

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