

# Drug Policy:

## Vectibix™ (panitumumab)

<b>POLICY NUMBER</b> UM ONC_1135	<b>SUBJECT</b> Vectibix™ (panitumumab)		<b>DEPT/PROGRAM</b> UM Dept	<b>PAGE 1 OF 3</b>
<b>DATES COMMITTEE REVIEWED</b> 07/22/11, 03/13/13, 07/24/14, 12/16/15, 12/29/16, 12/14/17, 11/09/18, 10/09/19, 12/11/19, 04/08/20, 02/10/21, 11/15/21, 01/12/22, 05/11/22, 01/11/23, 10/11/23, 10/09/24	<b>APPROVAL DATE</b> October 9, 2024	<b>EFFECTIVE DATE</b> October 25, 2024	<b>COMMITTEE APPROVAL DATES</b> 07/22/11, 03/13/13, 07/24/14, 12/16/15, 12/29/16, 12/14/17, 11/09/18, 10/09/19, 12/11/19, 04/08/20, 02/10/21, 11/15/21, 01/12/22, 05/11/22, 01/11/23, 10/11/23, 10/09/24	
<b>PRIMARY BUSINESS OWNER:</b> UM		<b>COMMITTEE/BOARD APPROVAL</b> Utilization Management Committee		
<b>NCQA STANDARDS</b> UM 2		<b>ADDITIONAL AREAS OF IMPACT</b>		
<b>CMS REQUIREMENTS</b>	<b>STATE/FEDERAL REQUIREMENTS</b>		<b>APPLICABLE LINES OF BUSINESS</b> Commercial, Exchange, Medicaid	

### I. PURPOSE

To define and describe the accepted indications for Vectibix (panitumumab) usage in the treatment of cancer, including FDA approved indications, and off-label indications.

Evolent is responsible for processing all medication requests from network ordering providers. Medications not authorized by Evolent may be deemed as not approvable and therefore not reimbursable.

The use of this drug must be supported by one of the following: FDA approved product labeling, CMS-approved compendia, National Comprehensive Cancer Network (NCCN), American Society of Clinical Oncology (ASCO) clinical guidelines, or peer-reviewed literature that meets the requirements of the CMS Medicare Benefit Policy Manual Chapter 15.

### II. INDICATIONS FOR USE/INCLUSION CRITERIA

#### A. Continuation requests for a not-approvable medication shall be exempt from this Evolent policy provided:

1. The requested medication was used within the last year, **AND**
2. The member has not experienced disease progression and/or no intolerance to the requested medication, **AND**
3. Additional medication(s) are not being added to the continuation request.

#### B. Colorectal Cancer

1. The member has KRAS/NRAS/BRAF wild-type gene advanced or metastatic colorectal cancer and Vectibix (panitumumab) will be used in **ANY** of the following clinical settings:
  - a. In combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or FOLFIRI (fluorouracil, leucovorin, and irinotecan) **OR**

- b. As a single agent or in combination with irinotecan for subsequent therapy following prior chemotherapy for metastatic disease.
  - c. Xeloda (capecitabine) may be substituted for 5-FU (5-fluorouracil) in the above mentioned 5-FU-based regimens
2. Vectibix (panitumumab) may be used as subsequent therapy in combination with Braftovi (encorafenib) for patients with unresectable/ metastatic disease (BRAF V600E mutation positive), regardless of KRAS/NRAS status.

### III. EXCLUSION CRITERIA

- A. Vectibix (panitumumab) use in member who has disease progression on Vectibix (panitumumab) or who has failed Erbitux (cetuximab).
- B. Absence of documented KRAS/NRAS/BRAF testing and results of such testing for the above indications.
- C. Dosing exceeds single dose limit of Vectibix (panitumumab) 6 mg/kg.
- D. Investigational use of Vectibix (panitumumab) with an off-label indication that is not sufficient in evidence or is not generally accepted by the medical community. Sufficient evidence that is not supported by CMS recognized compendia or acceptable peer reviewed literature is defined as any of the following:
  - 1. Whether the clinical characteristics of the patient and the cancer are adequately represented in the published evidence.
  - 2. Whether the administered chemotherapy/biologic therapy/immune therapy/targeted therapy/other oncologic therapy regimen is adequately represented in the published evidence.
  - 3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients. Generally, the definition of Clinically Meaningful outcomes are those recommended by ASCO, e.g., Hazard Ratio of less than 0.80 and the recommended survival benefit for OS and PFS should be at least 3 months.
  - 4. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover).
  - 5. That non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs.
  - 6. That case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.
  - 7. That abstracts (including meeting abstracts) without the full article from the approved peer-reviewed journals lack supporting clinical evidence for determining accepted uses of drugs.

### IV. MEDICATION MANAGEMENT

- A. Please refer to the FDA label/package insert for details regarding these topics.

### V. APPROVAL AUTHORITY

- A. Review – Utilization Management Department
- B. Final Approval – Utilization Management Committee

## VI. ATTACHMENTS

- A. None

## VII. REFERENCES

- A. Vectibix (panitumumab) prescribing information. Amgen Inc. Thousand Oaks, CA. 2023.
- B. Poulin-Costello M, et al. An analysis of the treatment effect of panitumumab on overall survival from a phase 3, randomized, controlled, multicenter trial (20020408) in patients with chemotherapy refractory metastatic colorectal cancer. *Target Oncol.* 2013 Jun;8(2):127-36. doi: 10.1007/s11523-013-0271-z
- C. Clinical Pharmacology Elsevier Gold Standard 2024.
- D. Micromedex® Healthcare Series: Thomson Micromedex, Greenwood Village, CO 2024.
- E. National Comprehensive Cancer Network. Cancer Guidelines and Drugs and Biologics Compendium 2024.
- F. AHFS Drug Information. American Society of Health-Systems Pharmacists or Wolters Kluwer Lexi-Drugs Bethesda, MD 2024.
- G. Ellis LM, et al. American Society of Clinical Oncology perspective: Raising the bar for clinical trials by defining clinically meaningful outcomes. *J Clin Oncol.* 2014 Apr 20;32(12):1277-80.
- H. Medicare Benefit Policy Manual Chapter 15 Covered Medical and Other Health Services: <https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/bp102c15.pdf>.
- I. Current and Resolved Drug Shortages and Discontinuations Reported to the FDA: <http://www.accessdata.fda.gov/scripts/drugshortages/default.cfm>.