

Clinical Policy Title: Panitumumab (Vectibix)

Policy Number: RxA.541

Drug(s) Applied: Panitumumab (Vectibix®)

Last Review Date: 01/2020

Line of Business: Commercial, HIM*, Medicaid, HIM-Medical Benefit

Background

Panitumumab (Vectibix®) is an epidermal growth factor receptor (EGFR) antagonist. It 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 (CRC):

- In combination with FOLFOX for first-line treatment
- As monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy

Limitation(s) of use: Vectibix is not indicated for the treatment of patients with *RAS*-mutant metastatic CRC or for whom *RAS* mutation status is unknown.

Indication	Dosing Regimen	Maximum Dose
CRC	6 mg/kg IV over 60 minutes (≤ 1000 mg) or 90 minutes (> 1000 mg) every 14 days	6 mg/kg

Single-dose vial for injection: 100 mg/5 mL, 400 mg/20 mL

Clinical Policy

Provider must submit documentation (such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

I. Initial Approval Criteria

A. Colorectal Cancer (must meet all):

1. Diagnosis of CRC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS*);
5. One of the following (a, b, c, or d):
 - a. Request is for first-line treatment: Prescribed in combination with FOLFOX or FOLFIRI (off-label);
 - b. Previous treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy (e.g., FOLFOXIRI);
 - c. Previous treatment with an oxaliplatin containing regimen (e.g., FOLFOX, CapeOx): Prescribed in combination with FOLFIRI, irinotecan, or irinotecan with Zelboraf® if BRAF V600E mutation positive (off-label);
 - d. Previous treatment with FOLFIRI: Prescribed in combination with irinotecan, or irinotecan with Zelboraf if BRAF V600E mutation positive (off-label);
6. Request meets one of the following (a or b):*

This clinical policy has been developed to authorize, modify, or determine coverage for individuals with similar conditions. Specific care and treatment may vary depending on individual need and benefits covered by the plan. This policy is not intended to dictate to providers how to practice medicine, nor does it constitute a contract or guarantee regarding payment or results. This document may contain prescription brand name drugs that are trademarks of pharmaceutical manufacturers that are not affiliated with RxAdvance.

- a. Dose does not exceed 6 mg/kg every 14 days;
- b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration:

Commercial/Medicaid – 6 months

HIM – 6 months for Vectibix 100 mg/5 mL

II. Continued Therapy

A. Colorectal Cancer (must meet all):

- 1. Currently receiving medication via RxAdvance benefit or documentation supports that member is currently receiving Vectibix for a covered indication and has received this medication for at least 30 days;
- 2. Member is responding positively to therapy;
- 3. If request is for a dose increase, request meets one of the following (a or b):*
 - a. New dose does not exceed 6 mg/kg every 14 days;
 - b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN

Approval duration:

Commercial/Medicaid – 12 months

HIM – 12 months for Vectibix 100 mg/5 mL

III. Appendices

Appendix A: Abbreviation/Acronym Key

CRC: colorectal cancer	KRAS: Kirsten rat sarcoma 2 viral oncogene homologue
EGFR: epidermal growth factor receptor	CRC: colorectal cancer
FDA: Food and Drug Administration	FOLFOXIRI: fluorouracil, leucovorin, oxaliplatin, irinotecan
FOLFIRI: fluorouracil, leucovorin, irinotecan	NRAS: neuroblastoma RAS viral oncogene homologue
FOLFOX: fluorouracil, leucovorin, oxaliplatin	

Appendix B: Therapeutic Alternatives

This table provides a listing of preferred alternative therapy recommended in the approval criteria. The drugs listed here may not be a formulary agent for all relevant lines of business and may require prior authorization.

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Modified FOLFOX 6	Day 1: oxaliplatin 85 mg/m ² IV Day 1: Folinic acid 400 mg/m ² IV Days 1–3: 5-FU 400 mg/m ² IV bolus on day 1, then 1,200 mg/m ² /day × 2 days (total 2,400 mg/m ² over 46–48 hours) IV continuous infusion Repeat cycle every 2 weeks.	See dosing regimen
CapeOX	Day 1: Oxaliplatin 130 mg/m ² IV Days 1–14: Capecitabine 1,000 mg/m ² PO BID Repeat cycle every 3 weeks.	See dosing regimen

FOLFIRI	Day 1: Irinotecan 180 mg/m ² IV Day 1: Leucovorin 400 mg/m ² IV Day 1: Flurouracil 400 mg/m ² IV followed by 2,400 mg/m ² continuous IV over 46 hours Repeat cycle every 14 days.	See dosing regimen
FOLFOXIRI	Day 1: Irinotecan 165 mg/m ² IV, oxaliplatin 85 mg/m ² IV, leucovorin 400 mg/m ² IV, flurouracil 1,600 mg/m ² continuous IV for 2 days (total 3,200 mg/m ²) Repeat cycle every 2 weeks.	See dosing regimen

Therapeutic alternatives are listed as Brand name® (generic) when the drug is available by brand name only and generic (Brand name®) when the drug is available by both brand and generic.

Appendix C: Contraindications/Boxed Warnings

- Contraindication(s): none reported
- Boxed warning(s): dermatologic toxicity

References

1. Vectibix Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; June 2017. Available at <https://www.vectibix.com/>. Accessed August 13, 2019.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 13, 2019.
3. National Comprehensive Cancer Network. Colon Cancer Version 2.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed August 13, 2019.
4. National Comprehensive Cancer Network. Rectal Cancer Version 2.2019. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed August 13, 2019.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020