RXADVANCE
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Clinical Policy Title:	panitumumab
Policy Number:	RxA.541
Drug(s) Applied	Vectibix®
Original Policy Date:	03/06/2020
Last Review Date:	12/07/2020
Line of Business Policy Applies to:	All lines of business

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.

Dosing Information

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

Dosage Forms

- Single-dose vial for injection: 100 mg/5 mL (20 mg/mL), 400 mg/20 mL (20 mg/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 or more;
4. Disease is wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS*);
5. Member has not had disease progression with cetuximab or panitumumab use

6. 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);
7. Request meets one of the following (a or b):*
   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: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. Colorectal Cancer (must meet all)**:**

1. Member is Currently receiving medication that has been authorized by RxAdvance, 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: 12 months
Medicaid: 12 months

III. Appendices

APPENDIX A: Abbreviation/Acronym Key

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

APPENDIX B: Therapeutic Alternatives

Below are suggested therapeutic alternatives based on clinical guidance. Please check drug formulary for preferred agents and utilization management requirements.

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

APPENDIX D: General Information

- In case of mild or moderate (Grade 1 or 2) infusion reactions, reduce infusion rate by 50% for the duration of that infusion. In case of severe (Grade 3 or 4) infusion reactions: Terminate the infusion. Permanently discontinue panitumumab depending on the severity and/or persistence of the reaction.

References

1. Vectibix® Prescribing Information. Thousand Oaks, CA: Amgen Inc.; June 2017. Available at https://www.vectibix.com/. Accessed October 10, 2020.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed October 10, 2020.
3. National Comprehensive Cancer Network. Colon Cancer Version 4.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed October 10, 2020.
4. National Comprehensive Cancer Network. Rectal Cancer Version 6.2020. Available at: https://www.nccn.org/professionals/physician_gls/pdf/rectal.pdf. Accessed October 10, 2020.
5. Clinical Pharmacology [database online] powered by ClinicalKey. Tampa, FL: Elsevier, 2020. Accessed with

subscription at: http://www.clinicalkey.com. Updated January 14, 2020. Accessed October 10, 2020.
6. Panitumumab, Lexi-Drug. Lexicomp. Wolters Kluwer Health, Inc. Riverwoods, IL. Accessed with subscription at: http://online.lexi.com. Accessed October 10, 2020.

Review/Revision History	Review/Revision Date	P&T Approval Date
Policy established.	01/2020	03/06/2020
Policy was reviewed: 1. Policy title table was updated: Line of business policy applies was updated to All lines of business. 2. Dosing Information: maximum dose was updated to 6 mg/kg IV every 14 days. 3. Added "Member has not had disease progression with cetuximab or panitumumab use" as a part of clinical criteria. 4. Appendix B: Pre table phrase was updated to *"Below are suggested therapeutic alternatives.."* 5. Appendix D: General Information was added. 6. References were updated.	10/10/2020	12/07/2020