Clinical Policy: Panitumumab (Vectibix)

Reference Number: PA.CP.PHAR.321
Effective Date: 01/2018
Last Review Date: 10/2022

Coding Implications
Revision Log

Description
Panitumumab (Vectibix®) is an epidermal growth factor receptor (EGFR) antagonist.

FDA Approved Indication(s)
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 (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.

Policy/Criteria
It is the policy of PA Health & Wellness ® that Vectibix is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Colorectal Cancer (must meet all):

1. Diagnosis of advanced, recurrent, or metastatic colorectal cancer (CRC);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is one of the following (a, b or c):
   a. Wild-type *RAS* (defined as wild-type in both *KRAS* and *NRAS*);
   b. BRAF wild-type;
   c. BRAF V600E mutation positive;
5. One of the following (a, b or c)*:
   a. Request is for first-line treatment: Prescribed in combination with FOLFOX or FOLFIRI or FOLFIRINOX (off-label);
   b. Prescribed as a single agent, in combination with FOLFIRI or FOLFOX or FOLFIRINOX, or in combination with irinotecan (off-label);
   c. Request is for BRAF V600E mutation positive disease: Prescribed in combination with Braftovi® (off-label);

   **Prior authorization may be required.*
6. 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)*.

Approval duration: 6 months

B. Other diagnoses/indications: Refer to PA.CP.PMN.53

II. Continued Approval

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

1. Currently receiving medication via PA Health & Wellness benefit or member has previously met all initial approval criteria; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies;
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).*

Approval duration: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**

1. Currently receiving medication via PA Health & Wellness benefit and documentation supports positive response to therapy; or the Continuity of Care policy (PA.LTSS.PHAR.01) applies; or
2. Refer to PA.CP.PMN.53

III. Appendices/General Information

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
CRC: colorectal cancer
FOLFOXIRI: fluorouracil, leucovorin, oxaliplatin, irinotecan
NRAS: neuroblastoma RAS viral oncogene homologue

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

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
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
Braftovi (Encorafenib)	300 mg PO once daily in combination with panitumumab (6 mg/kg IV every 14 days) until disease progression or unacceptable toxicity.	450 mg/day.

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

IV. Dosage and Administration

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

V. Product Availability

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

VI. References

1. Vectibix Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; August 2021. Available at https://www.vectibix.com/. Accessed August 9, 2022.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August 9, 2022.
3. National Comprehensive Cancer Network. Colon Cancer Version 1.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed August 9, 2022.

Coding Implications

Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

HCPCS Codes	Description
J9303	Injection, panitumumab, 10 mg

Reviews, Revisions, and Approvals	Date	Approval Date
4Q 2018 annual review: no significant changes; summarized NCCN and FDA-approved uses for improved clarity; added specialist involvement in care; references reviewed and updated.	07/2018	
4Q 2019 annual review: No changes per Statewide PDL implementation 01-01-2020	10/2019	
4Q 2020 annual review: added BRAF disease wild-type and for treatment in combination with Braftovi if BRAF V600E mutation position to colorectal indication as per NCCN 2A off label indication; references reviewed and updated.	08/2020	
4Q 2021 annual review: added that combination treatment with Vectibix and Braftovi is for advanced or metastatic disease per NCCN Compendium; for Vectibix prescribed as a single agent or in combination with irinotecan, added the option of previous oxaliplatin-based therapy without irinotecan or irinotecan-based therapy without oxaliplatin per NCCN Compendium; references reviewed and updated.	10/2021	
4Q 2022 annual review: added qualifiers that CRC is advanced, recurrent, or metastatic per NCCN; added BRAF V600E mutation positive criterion option to wild-type options as this mutation also allows for Vectibix administration per NCCN category 2A rating; updated combination regimens per NCCN; references reviewed and updated.	10/2022	