Clinical Policy: Panitumumab (Vectibix)

Reference Number: LA.PHAR.321
Effective Date: 11.04.23
Last Review Date: ~~04.22.24~~12.17.24 Coding Implications
Line of Business: Medicaid Revision Log

See Important Reminder at the end of this policy for important regulatory and legal information.

****Please note: This policy is for medical benefit****

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~~mCRC):

- 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

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

It is the policy of Louisiana Healthcare Connections® 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 CRC;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Disease is one of the following (a, b, c, d, or ~~e~~e):
   ~~a. Wild-type *RAS* (defined as wild-type in both~~ KRAS ~~and~~ /NRAS~~);~~
   ~~b.~~a./BRAF wild-type~~;~~ (i.e., no mutations in KRAS, NRAS, or BRAF genes);
   ~~c.~~b. BRAF V600E mutation positive;
   c. ~~One~~KRAS G12C mutation positive;
   d. Deficient mismatch repair/microsatellite instability-high (dMMR/MSI-H);
   e. Polymerase epsilon/delta (POLE/POLD1) mutation positive;
5. Prescribed in one of the following ways (a, b, c, d, or ~~e~~e)*:
   a. ~~Prescribed in~~ In combination with FOLFOX, CapeOX, or FOLFIRI ~~(off-label);;~~

b. ~~Request is for subsequent line treatment: Prescribed as~~As a single agent ~~or in~~;
~~b.~~c. In combination with irinotecan ~~(off-label);~~following prior therapy;
~~c.~~d. ~~Request is for~~If BRAF V600E mutation positive ~~disease: Prescribed in~~: In combination with Braftovi® ~~(off-label);~~following prior therapy;
e. If KRAS G12C mutation positive: In combination with Lumakras® or Krazati® following prior therapy;

**Prior authorization may be required.*

6. For colon cancer that is KRAS/NRAS/BRAF wild-type~~: colon~~ with unresectable synchronous metastases: Colon cancer is left-sided only (*see Appendix D*);
7. For dMMR/MSI-H or POLE/POLD1 mutation positive cancer: Member is ineligible for or has progressed on checkpoint inhibitor immunotherapy (*see Appendix B*);*

**Prior authorization may be required.*

~~7.~~8. 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: 6 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

II. Continued Therapy

A. Colorectal Cancer (must meet all)**:**
1. Currently receiving medication via Louisiana Healthcare Connections 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: 12 months

B. Other diagnoses/indications (must meet 1 or 2)**:**
1. If this drug has recently (within the last 6 months) undergone a label change (e.g., newly approved indication, age expansion, new dosing regimen) that is not yet reflected in this policy, refer to one LA.PMN.255
2. If the requested use (e.g., diagnosis, age, dosing regimen) is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized) AND criterion 1 above does not apply, refer to the off-label use policy LA.PMN.53

III. Diagnoses/Indications for which coverage is NOT authorized:

A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policy LA.PMN.53

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

CRC: colorectal cancer
CapeOX: capecitabine, oxaliplatin
dMMR/MSI-H: deficient mismatch repair/microsatellite instability-high
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
POLE/POLD1: polymerase epsilon/delta

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 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: Fluorouracil 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, fluorouracil 1,600 mg/m^2 continuous IV for 2 days (total 3,200 mg/m^2) Repeat cycle every 2 weeks.	See dosing regimen

Drug Name	Dosing Regimen	Dose Limit/ Maximum Dose
Checkpoint inhibitor therapies: Opdivo® (nivolumab) ± Yervoy® (ipilimumab) or Keytruda® (pembrolizumab)	Varies	Varies

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: KRAS/NRAS/BRAF Wild-Type Colon Cancer with Unresectable, Synchronous Liver and/or Lung Metastases

- The NCCN Colon Cancer Guidelines recommend that panitumumab should only be used for left-sided tumors in KRAS/NRAS/BRAF wild-type colon cancer~~.~~ with unresectable, synchronous liver and/or lung metastases. The NCCN defines the left side of the colon as splenic flexure to rectum. Evidence suggests that patients with tumors originating on the right side of the colon (hepatic flexure through cecum) are unlikely to respond to panitumumab. Data on the response to panitumumab in patients with primary tumors originating in the transverse colon (hepatic flexure to splenic flexure) are lacking.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
CRC	6 mg/kg IV over 60 minutes (≤ 1,000 mg) or 90 minutes (> 1,000 mg) every 14 days	6 mg/kg

VI. Product Availability

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

VII. References

1. Vectibix Prescribing Information. Thousand Oaks, CA: Amgen, Inc.; August 2021. Available at https://www.vectibix.com/. Accessed July ~~7, 2023~~17, 2024.
2. National Comprehensive Cancer Network Drugs and Biologics Compendium. Available at: http://www.nccn.org/professionals/drug_compendium. Accessed August ~~14, 2023~~8, 2024.
3. National Comprehensive Cancer Network. Colon Cancer Version ~~2.2023~~4.2024. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed August ~~14, 2023~~8, 2024.

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	LDH Approval Date
Converted corporate policy to local policy	06.26.23	10.05.23
Annual review simplified criteria by removing criterion qualifier "first-line treatment" as it overlaps with subsequent-line treatment regimens and to align with NCH criteria; added CapeOx as potential combination regimen per NCCN; added criterion that disease is left-sided only for colon cancer that is *KRAS/NRAS/BRAF* wild-type per NCCN & NCH, along with rationale in Appendix D; references reviewed and updated.	04.22.24	07.10.24
Per NCCN – added pathways for KRAS G12C, dMMR/MSI-H, and POLE/POLD1 mutations with corresponding requirements related to combination use and/or prior therapy; removed prior therapy requirement when requested for use as a single agent; modified requirement for left-sided colon cancer to only apply to unresectable synchronous metastases; references reviewed and updated.	12.17.24	

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. LHCC makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions, and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable LHCC administrative policies and procedures.

This clinical policy is effective as of the date determined by LHCC. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal

and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. LHCC retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment, or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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