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Medical benefit drug policies are a source for BCBSM and BCN medical policy information only. These documents are not to be used to determine benefits or reimbursement. Please reference the appropriate certificate or contract for benefit information. This policy may be updated and therefore subject to change.

P&T Date: 04/16/2026

Vectibix® (panitumumab)

HPCPS: J9303

Policy:

Requests must be supported by submission of chart notes and patient specific documentation.

A. Criteria:

- a. Prescribed by or in consultation with an oncologist or hematologist
- b. A confirmed diagnosis of 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 (mCRC) or other rare adenocarcinoma subtypes when used as:
 - i. First line therapy: In combination with FOLFOX (fluorouracil, leucovorin, oxaliplatin)
OR
 - ii. Second line therapy: In combination or as monotherapy following disease progression after prior treatment with standard therapy per NCCN guidelines
- c. In combination with sotorasib, for the treatment of adult patients with KRAS G12C-mutated mCRC, as determined by an FDA-approved test, who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy
- d. Should not be used if treatment failure has occurred with Vectibix or if there has been prior treatment with cetuximab
- e. Trial and failure, intolerance, or a contraindication to the preferred products as listed in the BCBSM/BCN utilization management medical drug list

B. Quantity Limitations, Authorization Period and Renewal Criteria

- a. Quantity Limits: Align with FDA recommended dosing
- b. Authorization Period: Aligns with FDA recommended or guideline supported treatment duration and provided for at least 60 days and up to 6 months at a time
- c. Renewal Criteria: Treatment may continue until disease progression or unacceptable toxicity

***Note: Coverage and approval duration may differ for Medicare Part B members based on any applicable criteria outlined in Local Coverage Determinations (LCD) or National Coverage Determinations (NCD) as determined by Center for Medicare and Medicaid Services (CMS). See the CMS website at <http://www.cms.hhs.gov/>. Determination of coverage of Part B drugs is based on medically accepted indications which have supported citations included or approved for inclusion determined by CMS approved compendia.

This policy and any information contained herein is the property of Blue Cross Blue Shield of Michigan and its subsidiaries, is strictly confidential, and its use is intended for the P&T committee, its members and BCBSM employees for the purpose of coverage determinations.

Background Information:

- Vectibix is an epidermal growth factor receptor (EGFR) antagonist indicated for the treatment of wild-type RAS metastatic colorectal cancer in combination with FOLFOX for first-line treatment, as monotherapy following disease progression after prior treatment with fluoropyrimidine, oxaliplatin, and irinotecan-containing chemotherapy, and in combination with sotorasib, for the treatment of adult patients with KRAS G12C-mutated mCRC who have received prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan-based chemotherapy. Wild-type RAS is defined as wild-type in both KRAS and NRAS as determined by an FDA-approved test. Vectibix is not indicated for the treatment of patients with RAS-mutant mCRC unless used in combination with sotorasib in KRAS G12C-mutated mCRC or for the treatment of patients with mCRC for whom RAS mutation status is unknown.
- The safety and efficacy of Vectibix was demonstrated in three large clinical trials, PRIME, ASPECCT, and CodeBreak 300. The PRIME study was a multicenter, phase 3 trial where patients with no prior chemotherapy for mCRC and available tissue for biomarker testing were randomly assigned 1:1 to receive Vectibix-FOLFOX4 versus FOLFOX4. KRAS results were available for 93% of the 1,183 patients randomly assigned. In the wild-type (WT) KRAS stratum, Vectibix-FOLFOX4 significantly improved progression free survival (PFS) compared with FOLFOX4. A nonsignificant increase in overall survival was also observed for Vectibix-FOLFOX4 versus FOLFOX4.
- The ASPECCT study was a randomized, multinational, open label, phase 3, head-to-head study that compared Vectibix to Erbitux® in patients with chemotherapy-refractory wild-type KRAS exon 2 metastatic colorectal cancer. The study enrolled and randomly allocated 1010 patients, 999 of whom began study treatment: 499 received Vectibix and 500 received Erbitux. For the primary analysis of overall survival, Vectibix was non-inferior to Erbitux. Median overall survival was 10.4 months with Vectibix and 10.0 months with Erbitux. Vectibix retained 105.7% of the effect of Erbitux on overall survival seen in this study.
- The CodeBreak 300 study was a randomized, open-label, active-controlled trial of 160 previously treated patients with KRAS G12C-mutated mCRC. Subjects were randomized 1:1:1 to receive Vectibix 6 mg/kg every 2 weeks plus sotorasib 960 mg daily, Vectibix 6 mg/kg every 2 weeks and sotorasib 240 mg daily, or investigator's choice of standard of care consisting of trifluridine/tipiracil or regorafenib. The primary endpoint is progression free survival (PFS). The trial demonstrated a statistically significant improvement in PFS for patients randomized to Vectibix in combination with sotorasib 960 mg compared to the investigator's choice of standard of care. The final analysis of overall survival was not statistically significant.
- There are no studies to support use of Vectibix following failure of its use. National Comprehensive Cancer Network 2025 colon cancer guidelines also do not recommend use of Vectibix or any other EGFR antagonist following a previous failure.

References:

1. Vectibix [prescribing information]. Thousand Oaks, CA: Amgen, Inc.; June 2025.
2. National Comprehensive Cancer Network. Colon cancer (Version 5.2025). 2025 Oct 30. Available at: https://www.nccn.org/professionals/physician_gls/pdf/colon.pdf. Accessed on February 24, 2026.
3. Douillard JY, Siena S, Cassidy J, et al. Randomized, phase III trial of panitumumab with infusional fluorouracil, leucovorin, and oxaliplatin (FOLFOX4) versus FOLFOX4 alone as first-line treatment in patients with previously untreated metastatic colorectal cancer: the PRIME study. *J Clin Oncol*. 2010 Nov 1; 28 (31): 4697 - 705.
4. Price TJ, Peeters M, K TW, et al. Panitumumab versus cetuximab in patients with chemotherapy-refractory wild-type KRAS exon 2 metastatic colorectal cancer (ASPECCT): a randomized, multicenter, open-label, non-inferiority phase 3 study. *Lancet Oncol*. 2014; 15: 569 - 79.
5. Fakih MG, Salvatore L, Esaki T, et al. Sotorasib plus panitumumab in refractory colorectal cancer with mutated KRAS G12C. *NEJM*. 2023 Oct 22; 389: 2125 – 39.

Policy History												
#	Date	Change Description										
2.3	Effective Date: 04/16/2026	Updated to include the trial and failure of preferred products statement										
2.2	Effective Date: 04/10/2025	Updated to include the new indication for use in combination with sotorasib, for the treatment of adult patients with KRAS G12C-mutated mCRC										
2.1	Effective Date: 02/13/2025	Annual review of criteria was performed, no changes were made										
2.0	Effective Date: 02/08/2024	Annual review of criteria was performed, no changes were made										
1.9	Effective Date: 02/02/2023	Updated approval length to allow for FDA recommended dosing for at least 60 days										
1.8	Effective Date: 10/06/2022	Updated approval length to allow for FDA recommended dosing or up to 6 months at a time										
1.7	Effective Date: 10/07/2021	Annual review of criteria was performed, no changes were made										
1.6	Effective Date: 12/01/2020	UM medical management system update for BCBS <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>Yes</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	Yes	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCBS	Yes											
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BCNA	Yes											
1.5	Effective Date: 10/08/2020	Annual Review										
1.4	Effective Date: 01/01/2020	UM medical management system update for BCNA and MAPPO <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>Yes</td></tr><tr><td>BCNA</td><td>Yes</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	Yes	BCNA	Yes
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BCBS	No											
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1.3	Effective Date: 11/07/2019	Annual Review of Medical Policy										
1.2	Effective Date: 08/01/2019	UM medical management system update for BCN <table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>Yes</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>	Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	Yes	MAPPO	No	BCNA	No
Line of Business	PA Required in Medical Management System (Yes/No)											
BCBS	No											
BCN	Yes											
MAPPO	No											
BCNA	No											
1.1	Effective Date: 11/01/2018	Updated criteria per oncology vendor										

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1.0	Effective Date: 02/08/2018	New policy created										
<table><tr><th>Line of Business</th><th>PA Required in Medical Management System (Yes/No)</th></tr><tr><td>BCBS</td><td>No</td></tr><tr><td>BCN</td><td>No</td></tr><tr><td>MAPPO</td><td>No</td></tr><tr><td>BCNA</td><td>No</td></tr></table>			Line of Business	PA Required in Medical Management System (Yes/No)	BCBS	No	BCN	No	MAPPO	No	BCNA	No
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* The prescribing information for a drug is subject to change. To ensure you are reading the most current information it is advised that you reference the most updated prescribing information by visiting the drug or manufacturer website or <http://dailymed.nlm.nih.gov/dailymed/index.cfm>.