SmartHealth Ascension

Panitumumab

(Vectibix®) J9303 (10 mg)

Covered with prior authorization

Requests for Vectibix® (panitumumab) may be approved if the following criteria are met:

- Individual has a diagnosis of stage IV colon, rectal, colorectal, appendiceal, or anal adenocarcinoma and the following are met: (Label, NCCN 2A)
    - Panitumumab is used as a single agent or as part of combination therapy; **AND**
    - Extended RAS gene mutation testing with an FDA approved test is confirmed and the tumor is determined to be RAS wild-type*****; **AND**
    - Panitumumab is used in a single line of therapy; **AND**
    - Panitumumab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab) (NCCN 2A); **AND**
    - The individual has not received prior treatment****** with cetuximab (NCCN 2A);

OR

- Individual has a diagnosis of unresectable, advanced, or metastatic colorectal cancer and the following are met (Label, NCCN 2A):
    - Individual has BRAF V600E mutation with test results confirmed; **AND**
    - Panitumumab is used in combination with encorafenib; **AND**
    - Individual has demonstrated disease progression after one or more prior lines of systemic therapy; **AND**
    - Panitumumab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab); **AND**
    - Panitumumab is used in a single line of therapy; **AND**
    - Individual has not received prior treatment****** with cetuximab.

***Note**: RAS wild-type means that the KRAS and NRAS genes are normal or lacking mutations.
****Note**: A course of cetuximab discontinued because of adverse reaction, not progressive disease, is not considered prior treatment.

Requests for Vectibix® (panitumumab) may **not** be approved if the above criteria are not met and for all other indications not included above.

Initial and renewal authorizations are for up to 12 months.

Annual reauthorizations will require medical chart documentation that the patient has been seen within the past 12 months and that markers of disease are improved by therapy.

When coverage is available and medically necessary, the dosage, frequency, duration of therapy, and site of care should be reasonable, clinically appropriate, and supported by evidence-based literature and adjusted based upon severity, alternative available treatments, and previous response to therapy.

Deleted codes and codes which are not effective at the time the service is rendered may not be eligible for reimbursement.

Exclusion criteria:

- Vectibix® (panitumumab) may not be approved when the above criteria are not met and for all other indications.
- Doses, durations, or dosing intervals that exceed FDA maximum limits for any FDA-approved indication or are not supported by industry-accepted practice guidelines or peer-reviewed literature for the relevant off-label use.
- Individuals with significant known risk factors unless the record provides an assessment of clinical benefit that outweighs the risk.
- Treatment of RAS-mutant metastatic colorectal cancer, small bowel or anal adenocarcinoma, (that is, when an FDA approved test has confirmed the presence of genetic mutations in any of the RAS genes) or when RAS mutation status unknown.
- In combination with other monoclonal antibodies or anti-VEGF agents.
- Treatment of penile cancer.
- Treatment of squamous cell anal carcinoma.

U.S. Food and Drug Administration:
This section is to be used for informational purposes. FDA approval alone is not a basis for coverage. Vectibix® is a human monoclonal antibody that targets and inhibits the biologic activity of the human epidermal growth factor receptor (EGFR) that is primarily used to treat colorectal cancer. The FDA approved indications for Vectibix® include as first line therapy in combination with FOLFOX (fluorouracil, leucovorin, and oxaliplatin) or as monotherapy following disease progression after prior treatment with fluoropyrimidine-, oxaliplatin-, and irinotecan containing chemotherapy. The National Comprehensive Cancer Network® (NCCN) provides additional recommendations with a category 2A level of evidence for the use of Vectibix®. NCCN recommends appendiceal adenocarcinoma be treated with chemotherapy according to colon cancer guidelines. Similarly, it is recommended that anal adenocarcinoma, a rare histologic form of anal cancer, may be treated according to guidelines for rectal cancer. The FDA label includes the requirement for confirmed RAS wild-type histology and that Vectibix® is not indicated for those with somatic RAS mutations in either KRAS or NRAS or for whom RAS mutation status is unknown. NCCN also notes that research has demonstrated that mutations in the KRAS, and more recently NRAS genes, are a predictive factor for a lack of response to Vectibix® therapy for colorectal cancer. Mutations in the BRAF gene cause a cancer signal downstream of the EGFR/RAS pathway. In the presence of BRAF mutations, NCCN notes that response to EGFR inhibitors is very unlikely unless given with a BRAF inhibitor. NCCN recommends the combination use of Vectibix® and encorafenib for BRAF mutation positive colorectal cancer after prior therapy. Vectibix® and Erbitux (cetuximab) are two EGFR antagonists approved by the FDA. There is currently no evidence to support switching to either Erbitux or Vectibix® after failure of the other drug and NCCN recommends against this practice. In addition, studies have shown that combination with more than one biologic agent is not associated with improved outcomes and can cause increased toxicity, specifically regarding the addition of Erbitux or Vectibix® to a bevacizumab-containing regimen (Tol 2009, Hecht 2009). NCCN strongly recommends against the use of therapy involving concurrent combinations of an anti-EGFR agent and an anti-VEGF agent.

Other Uses
NCCN no longer recommends the off-label use of Vectibix® as second-line palliative therapy in penile cancer. FDA label and compendia do not support this indication either. Though anal adenocarcinoma is an acceptable use for Vectibix®, NCCN guidelines for squamous cell anal cancer, the most common type of anal cancer, do not currently include Vectibix® among recommended treatments. NCCN guideline for small bowel adenocarcinoma (SBA) notes that cetuximab and panitumumab should not be used to treat SBA due to inconclusive evidence.

Vectibix® has a **black box warning** for dermatologic toxicity. Dermatologic toxicities occurred in 90% of patients and were severe (NCICTC grade 3 and higher) in 15% of patients receiving Vectibix® monotherapy.

Key References Accessed 8/2022:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2022. URL: http://www.clinicalpharmacology.com. Updated periodically.
2. DailyMed. Package inserts. U.S. National Library of Medicine, National Institutes of Health website. http://dailymed.nlm.nih.gov/dailymed/about.cfm.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2022; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2022 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp.
    a. Anal Carcinoma. V1.2022. Revised March 2, 2022.
    b. Colon Cancer. V1.2022. Revised February 25, 2022.
    c. Rectal Cancer. V1.2022. Revised February 25, 2022.

Date	Summary of Changes
August 2022	Criteria for use summary developed by the Ascension Medical Specialty Prior Authorization Team.
September 2022	Criteria for use summary approved by the Ascension Ambulatory Care Expert Review Panel.
October 2022	Criteria for use summary approved by the Ascension Therapeutic Affinity Group.

If you have questions, call 833-980-2352 to speak to a member of the Ascension Rx prior authorization team, or email your questions to smarthealthspecialty@ascension.org.