Vectibix (panitumumab)

Override	Approval Duration
Prior Authorization	1 year

Medication
Vectibix (panitumumab)

APPROVAL CRITERIA:

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

I. Individual has a diagnosis of stage IV colon, rectal, colorectal, appendiceal, or anal adenocarcinoma and the following are met (Label, NCCN 2A):
   A. Panitumumab is uses as a single agent or as part of combination therapy; AND
   B. Extended RAS gene mutation testing with an FDA approved test is confirmed and the tumor is determined to be RAS wild-type (RAS wild-type means that the KRAS and NRAS genes are normal or lacking mutations); AND
   C. Panitumumab used in a single line of therapy; AND
   D. Panitumumab is not used in combination with anti-VEGF agents (bevacizumab, ziv-aflibercept, or ramucirumab) (NCCN 2A); AND

OR

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

Requests for Vectibix (panitumumab) may not be approved for the following:

I. All other indications not included above; **OR**
II. 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 is unknown; **OR**
III. In combination with other monoclonal antibodies or anti-VEGF agents; **OR**
IV. Treatment of penile cancer; **OR**
V. Treatment of squamous cell anal carcinoma; **OR**
VI. Individual has received prior treatment with cetuximab (cetuximab discontinuation due to adverse reaction is not considered prior treatment).

Note:
Vectibix (panitumumab) has a black box warning for dermatologic toxicity. Dermatologic toxicities occurred in 90% of patients and were severe (NCI-CTC grade 3 and higher) in 15% of patients receiving Vectibix monotherapy.

Key References:

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.: 2023. 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. Accessed: March 13, 2023.
3. DrugPoints® System [electronic version]. Truven Health Analytics, Greenwood Village, CO. Updated periodically.
4. Lexi-Comp ONLINE™ with AHFS™, Hudson, Ohio: Lexi-Comp, Inc.; 2023; Updated periodically.
5. NCCN Clinical Practice Guidelines in Oncology™. © 2023 National Comprehensive Cancer Network, Inc. For additional information visit the NCCN website: http://www.nccn.org/index.asp. Accessed on March 16, 2023.
    a. Colon Cancer. V1.2023. Revised March 29, 2023.
    b. Rectal Cancer. V1.2023. Revised March 29, 2023.

Federal and state laws or requirements, contract language, and Plan utilization management programs or polices may take precedence over the application of this clinical criteria.