I. Medication Description

Vectibix is a recombinant, human IgG2 kappa monoclonal antibody that binds to epidermal growth factor receptor (EGFR) on the surface of normal and tumor cells. The binding inhibits the activation cascade that leads to cancer cell growth, survival, motility, proliferation and transformation.

Vectibix is indicated for the treatment of EGFR-expressing, metastatic colorectal carcinoma in patients that experienced disease progression on or after using a fluoropyrimidine-, oxaliplatin-, and/or irinotecan-containing chemotherapy regimens.

II. Position Statement

Coverage is determined through a prior authorization process with supporting clinical documentation for every request.

III. Policy

Coverage for Vectibix® is provided for adult patients aged 18 years and older when the following criteria are met:

- Patient has a diagnosis of metastatic or locally unresectable colorectal cancer AND
- The tumor expresses KRAS/NRAS wild-type gene AND
- Patient has not been previously treated with cetuximab or panitumumab AND
- Drug is used as a single agent or as part of combination treatment (with FOLFOX, FOLFIRI, or irinotecan)

IV. Quantity Limitations

- No more than 70 billable units (700mg) in a single administration AND
- No more than 70 billable units (700mg) every 14 days

V. Coverage Duration

Coverage will be provided for 6 months and may be renewable for additional 6 month intervals.
VI. **Coverage Renewal Criteria**

Coverage can be renewed based upon the following criteria:

- Tumor response with stabilization of disease, lack of disease progression, or decrease in size of tumor or tumor spread **AND**
- Absence of unacceptable toxicity from the drug

VII. **Billing/Coding Information**

- J9303: Injection, panitumumab, 10 mg
- Pertinent diagnosis- Colorectal cancer: C17.0-C17.2, C17.8, C17.9, C18.0-C18.9, C19, C20, C21.8, C78.00-C78.02, C78.6, C78.7, Z85.038

VIII. **Summary of Policy Changes**

- 9/1/11: Updated to match current NCCN guidelines indicating first-line usage and single agent usage; Coverage duration changed to a standard 6 month timeframe.
- 9/15/12: Addition of penile cancer indication; Clarification of whenVectibix can be used for relapsed/refractory colorectal cancer
- 9/15/13: KRAS mutation positive added to exclusions; Quantity limitations updated.
- 3/15/14: updated policy criteria to match updated NCCN guidelines
- 3/15/15: removed coverage for penile cancer, simplification of coverage criteria for colorectal cancer
- 7/1/15: formulary distinctions made
- 3/15/16: updated coverage to coincide with current NCCN treatment guidelines
- 1/1/17: no policy changes

IX. **References**

1. UpToDate Online, retrieved March 2011.

The Plan fully expects that only appropriate and medically necessary services will be rendered. The Plan reserves the right to conduct pre-payment and post-payment reviews to assess the medical appropriateness of the above-referenced therapies.

Drug therapy initiated with samples will not be considered as meeting medical necessity for coverage for non-preferred or prior authorized medications.

The preceding policy is a guideline to allow for coverage of the pertinent medication/product, and is not meant to serve as a clinical practice guideline.