

Title: panitumumab (Vectibix)

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| Origination: 08/19/10 | Revised: | Annual Review: 12/15/11 |
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Purpose:

To provide guidelines and criteria for the review and decision determination of requests for medications that requires prior authorization.

Background Information:

Reference Statement

- Guidelines are compiled from available US Food and Drug Administration (FDA) approved indications, general practice guidelines, and/or evidence-based uses established through phase III clinical studies without published conflicting data. Only clinical studies published in their entirety in reputable peer-reviewed journals will be evaluated.

Medication Summary

- Panitumumab is a recombinant, human IgG2 kappa monoclonal antibody that binds specifically to the human epidermal growth factor receptor (EGFR).
- Panitumumab is indicated as a single agent for the treatment of epidermal growth factor receptor (EGFR)-expressing, metastatic colorectal carcinoma (mCRC) with disease progression on or following fluoropyrimidine-, oxaliplatin-, and irinotecan-containing chemotherapy regimens.
- Panitumumab is a fully human monoclonal antibody that binds specifically with high affinity to the EGFR, HER1, c-ErbB-1 on both normal and tumor cells. Panitumumab blocks the binding of ligands to the epidermal growth factor receptor (EGFR). Epidermal growth factor and tissue growth factor- α regulate cell proliferation and differentiation through binding to EGFR. The binding of panitumumab to EGFR leads to internalization of the receptor preventing further activation and blocks phosphorylation and activation of receptor-associated kinases thus inhibiting subsequent signaling of a variety of cellular events.
- The recommended dose of panitumumab is 6 mg/kg, administered as an intravenous infusion over 60 minutes, every 14 days. Doses higher than 1000 mg should be administered over 90 minutes. *For mild or moderate (Grade 1 or 2) infusion reactions:* Reduce infusion rate by 50% for the duration of that infusion. *For severe (Grade 3 or 4) infusion reactions:* Panitumumab should be immediately and permanently discontinued.

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Background Information, continued:

Eligibility Criteria

- Member must be eligible and have applicable benefits.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Exclusions

- Members with a history of hypersensitivity to panitumumab or any of its ingredients.

Procedure:

- 1.0 Request for *initial therapy* with Vectibix for **metastatic colorectal cancer (mCRC)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 1.1 Member has undergone KRAS mutation analysis to assure response to therapy;
 - 1.2 If all criteria are met, Vectibix may be approved for six (6) months.
- 2.0 Request for *continuation of therapy* beyond initial authorization period of Vectibix for **metastatic colorectal cancer (mCRC)** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying the following:
 - 2.1 Tumor response;
 - 2.2 If all criteria are met, Vectibix may be approved for six (6) months.

References:

1. Vectibix (package insert). Thousand Oaks, CA: Amgen, Inc; 2007.
2. Facts and Comparisons 4.0, St. Louis, MO. Walters Kluwer Health URL: www.factsandcomparisons.com Updated 2010.

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Disclaimer Information:

Prior Authorization criteria are developed to determine coverage for AvMed Health Plans' benefits, and are published to provide a better understanding of the basis upon which coverage decisions are made. AvMed Health Plans makes coverage decisions based on the Member's benefit plan contract and these criteria. This guideline sets forth concise clinical coverage criteria which have been developed from a review of current literature, policies of the FDA and other government agencies, and other appropriate references, in consultation and with approval from practicing physicians who are members of AvMed's Pharmacy and Therapeutic committee. Treating providers are solely responsible for the medical advice and treatment of Members. This guideline may be updated and therefore is subject to change. The use of these criteria is neither a guarantee of payment nor a final prediction of how specific claim(s) will be adjudicated.