

Title: *bevacizumab (Avastin)*

Origination: 07/28/10	Revised: 03/25/11	Annual Review: 12/15/11
------------------------------	--------------------------	--------------------------------

Purpose:

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

Background Information:

Medication Summary

- Avastin (bevacizumab) is a recombinant humanized monoclonal IgG1 antibody that binds to and inhibits the biologic activity of human vascular endothelial growth factor (VEGF) in *in vitro* and *in vivo* assay systems.
- Avastin is indicated for:
 - First- or second-line treatment of Members with metastatic carcinoma of the colon or rectum in combination with intravenous 5-fluorouracil-based chemotherapy;
 - First-line treatment of unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer in combination with carboplatin and paclitaxel;
 - Treatment of patients who have not received chemotherapy for metastatic HER2-negative breast cancer in combination with paclitaxel;
 - Treatment of glioblastoma with progressive disease following prior therapy as a single agent;
 - Treatment of metastatic renal cell carcinoma in combination with interferon alfa.
- Recommended doses include:
 - **Metastatic Colorectal Cancer (mCRC):** 5 mg/kg or 10 mg/kg every two (2) weeks when used in combination with intravenous 5-FU-based chemotherapy:
 - Administer 5 mg/kg when used in combination with bolus-IFL;
 - Administer 10 mg/kg when used in combination with FOLFOX4,
 - **Non-Squamous Non-Small Cell Lung Cancer (NSCLC):** 15 mg/kg every 3 weeks in combination with carboplatin and paclitaxel;
 - **Metastatic Breast Cancer (MBC):** 10 mg/kg every two (2) weeks in combination with paclitaxel;
 - **Glioblastoma:** 10 mg/kg every two (2) weeks;
 - **Metastatic Renal Cell Carcinoma (mRCC):** 10 mg/kg every two (2) weeks in combination with interferon alfa.

Title: bevacizumab (Avastin)

Background Information, continued:

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.

Eligibility Criteria

- Member must be eligible and have applicable benefit coverage (i.e., self-injectable rider) within the specified date(s) of service.
- Prior authorization requests that do not meet clinical criteria in this Procedure will be forwarded to a Clinical Pharmacist for review.

Procedure:

- 1.0 Request for initial therapy with Avastin for **Metastatic carcinoma of the colon or rectum** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 1.1 Combination with intravenous (IV) 5-fluorouracil or capecitabine (Xeloda) based chemotherapy for treatment of patients with metastatic carcinoma of the colon or rectum;
 - 1.2 If criteria are met, Avastin is approvable for six (6) months.
- 2.0 Request for initial therapy with Avastin for **Non-squamous non-small cell lung cancer** requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 2.1 Combination with carboplatin or cisplatin based chemotherapy for the first line treatment of Member with unresectable, locally advanced, recurrent or metastatic nonsquamous non-small cell lung cancer;
 - 2.2 If criteria are met, Avastin is approvable for six (6) months.

Title: bevacizumab (Avastin)

Procedure, continued:

- 3.0 Request for initial therapy with Avastin for **HER2 negative metastatic breast cancer**, requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying all of the following:
 - 3.1 Combination with paclitaxel for the treatment of Member who has not received chemotherapy for metastatic human epidermal growth factor receptor 2 (HER2)-negative breast cancer;
 - 3.2 If criteria are met, Avastin is approvable for six (6) months.
- 4.0 Request for initial therapy with Avastin for **renal cell carcinoma**, requires documentation from the Member's medical records maintained by the requesting independent practitioner:
 - 4.1 Avastin is approvable for six (6) months.
- 5.0 Request for initial therapy with Avastin for **Primary Central nervous system cancer**, requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying:
 - 5.1 Member has relapsed or has recurrence;
 - 5.2 If criteria are met, Avastin is approvable for six (6) months.
- 6.0 Request for initial therapy with Avastin for **Cervical Cancer**, requires documentation from the Member's medical records maintained by the requesting independent practitioner verifying:
 - 6.1 Avastin is being used as 2nd line therapy;
 - 6.2 If criteria are met, Avastin is approvable for six (6) months.
- 7.0 Request for initial therapy with Avastin for **Ovarian Cancer**, requires documentation from the Member's medical records maintained by the requesting independent practitioner:
 - 7.1 Avastin is approvable for six (6) months.

Title: bevacizumab (Avastin)

Procedure, continued:

8.0 Request for initial therapy with Avastin for **Soft Tissue Sarcoma**, requires documentation from the Member's medical records maintained by the requesting independent practitioner:

8.1 Avastin is approvable for six (6) months.

References:

1. Avastin (bevacizumab) Prescribing Information. Genentech, Inc. San Francisco, Ca. Revised July 2009.
2. Facts and Comparisons 4.0, St. Louis, MO. Walters Kluwer Health URL: www.factsandcomparisons.com. Updated 2010.
3. National Comprehensive Cancer Network, Inc. (NCCN) Practice Guidelines in Oncology Version 2.2010, March 2010. Available at: www.nccn.org/professionals/physician_gls/f_guidelines.asp

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.