# Clinical Policy: Bevacizumab (Avastin)

Reference Number: CP.PHAR.93
Effective Date: 12/11
Last Review Date: 04/17

Coding Implications
Revision Log

**See Important Reminder at the end of this policy for important regulatory and legal information.**

**Description**
The intent of the criteria is to ensure that patients follow selection elements established by Centene® clinical policy for bevacizumab (Avastin®).

**Policy/Criteria**
It is the policy of health plans affiliated with Centene Corporation® that Avastin is **medically necessary** when the following criteria are met:

**I. Initial Approval Criteria**

**A. Colorectal Cancer** (must meet all):

1. Age ≥ 18 years;
2. Meets a or b:
   a. FDA approved use:
      i. Colorectal cancer (a or b):
         a) Primary or subsequent therapy for metastatic disease:
            1) In combination with 5-FU-based therapy*;
         b) Subsequent therapy for metastatic disease:
            1) In combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based therapy* after disease progression on a first-line Avastin-containing regimen;
   b. Off-label NCCN approved use:
      i. Colorectal cancer (a or b):
         a) Primary or subsequent therapy for unresectable, metastatic or medically inoperable disease (1, 2 or 3):
            1) In combination with capecitabine, FOLFOX, FOLFIRI, CapeOX, FOLFOXIRI, or 5-FU/LV*;
            2) In combination with irinotecan;
            3) In combination with irinotecan and oxaliplatin;
         b) Adjuvant therapy for resectable metastases:
            1) In combination with capecitabine, FOLFOX, FOLFIRI, CapeOX, FOLFOXIRI, or 5-FU/LV*;
      ii. Rectal cancer:
         a) Primary therapy for resectable disease classified as either (T3/N0/M0 [stage IIA]) or (anyT/N1-2/M0 [stage III])**:
            1) In combination with capecitabine, FOLFOX, FOLFIRI, FOLFOXIRI, CapeOX, or 5-FU/LV*;
3. Member's history is negative for the following:
   a. Serious hemorrhage or recent hemoptysis;
   b. Surgery within the last 28 days and unhealed surgical wounds.

**Examples of fluoropyrimidines: Capecitabine, floxuridine, fluorouracil (5-FU); examples of fluoropyrimidine-based regimens: 5-FU/LV (fluorouracil, leucovorin); FOLFOX (5-FU, leucovorin, oxaliplatin); FOLFIRI (5-FU, leucovorin, irinotecan); FOLFOXIRI (5-FU, leucovorin, oxaliplatin, irinotecan); CapeOX (capecitabine, oxaliplatin).*
***American Joint Committee on Cancer (TNM staging classification (7th ed., 2010) as reported in NCCN Colon and Rectal Cancer: T (primary tumor characteristics), N (regional lymph node status), M (metastasis status).*

**Approval duration: 6 months**

**B. Non-Squamous Non-Small Cell Lung Cancer** (must meet all):
1. Age ≥ 18 years;
2. Non-squamous non-small cell lung cancer;
3. Meets a or b:
   a. FDA approved use:
      i. Primary therapy for unresectable, locally advanced, recurrent or metastatic disease:
         a) In combination with carboplatin and paclitaxel;
   b. Off-label NCCN recommended use (i or ii):
      i. Primary or subsequent therapy for unresectable, locally advanced, recurrent or metastatic disease (a, b, c or d):
         a) In combination with carboplatin and paclitaxel;
         b) In combination with carboplatin and pemetrexed;
         c) In combination with pemetrexed;
         d) In combination with cisplatin and pemetrexed;
      ii. Continuation maintenance therapy (if prior Avastin use associated with achievement of tumor response or stable disease) (a or b):
         a) As single agent;
         b) In combination with pemetrexed;
4. Member's history is negative for the following:
   a. Serious hemorrhage or recent hemoptysis;
   b. Surgery within the last 28 days and unhealed surgical wounds.

**Approval duration: 6 months**

**C. Glioblastoma** (must meet all):
1. Age ≥ 18 years;
2. Glioblastoma;
3. Meets a or b:
   a. FDA approved use:
      i. Subsequent therapy for recurrent or progressive disease;
         a) As single agent;
   b. Off-label NCCN recommended use:
      i. Subsequent therapy for recurrent or progressive disease:
         a) In combination with irinotecan, carmustine, lomustine, temozolomide, or carboplatin;

4. Member's history is negative for the following:
   a. Serious hemorrhage or recent hemoptysis;
   b. Surgery within the last 28 days and unhealed surgical wounds.

**Approval duration: 6 months**

**D. Renal Cell Carcinoma** (must meet all):
1. Age ≥ 18 years;
2. Renal cell carcinoma;
3. Meets a or b:
   a. FDA approved use:
      i. Metastatic disease:
         a) In combination with interferon alfa-2a/2b;
   b. Off-label NCCN recommended use:
      i. Relapsed or stage IV (advanced or metastatic) disease (a, b or c):
         a) Clear cell histology - primary therapy:
            1) In combination with interferon alfa-2b;
         b) Clear cell histology - subsequent therapy:
            1) As single agent;
         c) Non-clear cell histology:
            1) As single agent;
4. Member's history is negative for the following:
   a. Serious hemorrhage or recent hemoptysis;
   b. Surgery within the last 28 days and unhealed surgical wounds.

**Approval duration: 6 months**

**E. Carcinoma of the Cervix** (must meet all):
1. Age ≥ 18 years;
2. Cervical carcinoma;
3. Meets a or b:
   a. FDA approved use:
      i. Persistent, recurrent or metastatic disease (a or b):
         a) In combination with paclitaxel and cisplatin;
         b) In combination with paclitaxel and topotecan;
   b. Off-label NCCN recommended use:
      i. Persistent, recurrent or metastatic disease (a or b):
         a) Primary therapy (1 or 2):
            1) In combination with carboplatin;
            2) In combination with topotecan;
         b) Subsequent therapy:
            1) As single agent;
4. Member's history is negative for the following:
   a. Serious hemorrhage or recent hemoptysis;
   b. Surgery within the last 28 days and unhealed surgical wounds.

**Approval duration: 6 months**

**F. Epithelial Ovarian/Fallopian Tube/Primary Peritoneal Cancer** (must meet all):
1. Age ≥ 18 years;
2. Meets a or b:
   a. FDA approved use (i or ii):
      i. Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer:
         a) Persistent/recurrent platinum-resistant disease:
            1) In combination with paclitaxel;
            2) In combination with pegylated liposomal doxorubicin;
            3) In combination with topotecan;
         b) Persistent/recurrent platinum-sensitive disease:
            1) In combination with carboplatin and paclitaxel;
            2) In combination with carboplatin and gemcitabine;
            3) As single agent;
   b. Off-label NCCN recommended use (i, ii, iii, iv or v):
      i. Epithelial ovarian cancer, fallopian tube cancer, or primary peritoneal cancer:
         a) Persistent/recurrent disease:
            1) As single-agent;
         b) Unresectable disease – primary therapy:
            1) In combination with carboplatin and paclitaxel;
         c) Stage II-IV disease post completion surgery* - adjuvant therapy:
            1) In combination with carboplatin and paclitaxel;
      ii. Granulosa cell tumor** (relapsed stage II-IV disease) – subsequent therapy:
         a) As single-agent;
      iii. Serous/endometrioid epithelial carcinoma (stage II-IV low-grade [grade 1]) - adjuvant therapy:
         a) In combination with carboplatin and paclitaxel;
      iv. Mucinous carcinoma of the ovary (stage II-IV) - adjuvant therapy:
         a) In combination with carboplatin and paclitaxel;
3. Member's history is negative for the following:
   a. Serious hemorrhage or recent hemoptysis;
   b. Surgery within the last 28 days and unhealed surgical wounds.

_____
**Follow-up surgery performed if fertility-conserving strategies are no longer desired.*
***A type of malignant sex cord-stromal tumor.*

**Approval duration: 6 months**

**G. Other diagnoses/indications:** Refer to CP.PHAR.57 - Global Biopharm Policy.
1. Oncology: The following NCCN recommended uses meeting NCCN categories 1, 2a or 2b are approved per the CP.PHAR.57 Global Biopharm Policy:
   a. Age ≥ 18 years;
      i. Breast cancer;
      ii. Endometrial carcinoma;
      iii. Malignant pleural mesothelioma;

iv. Primary central nervous system cancers (a or b):
  a) Adult intracranial and spinal ependymoma (excluding subependymoma);
  b) Anaplastic glioma;
v. Soft tissue sarcoma (a or b):
  a) Angiosarcoma;
  b) Solitary fibrous tumor/hemangiopericytoma;

2. Ophthalmology (intravitreal administration):
   a. Retinopathy of prematurity;
   b. Age ≥ 18 years:
      i. Neovascular glaucoma;
      ii. Neovascular (wet) age-related macular degeneration;
      iii. Diabetic retinopathy;
      iv. Macular edema secondary to (a or b):
        a) Branch or central retinal vein occlusion;
        b) Diabetes;
      v. Choroidal/retinal neovascularization secondary to (a or b):
        a) Pathologic myopia;
        b) Angioid streaks;
3. Member's current history is negative for the following:
   a. Serious hemorrhage or recent hemoptysis;
   b. Surgery within the last 28 days and unhealed surgical wounds.

**Approval duration: 6 months**

**II. Continued Approval**

**A. All Indications** (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met all initial approval criteria;
2. Documentation of positive response to therapy (e.g.: no disease progression, not experiencing unacceptable toxicity);
3. If use is ophthalmic, evidence of detained neovascularization or improvement in visual acuity.

**Approval duration: 12 months**

**B. Other diagnoses/indications** (must meet 1 or 2)**:**

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
   **Approval duration: Duration of request or 6 months (whichever is less);** or
2. Refer to CP.PHAR.57 – Global Biopharm Policy.

**Background**

*Description/Mechanism of Action:*

Bevacizumab binds vascular endothelial growth factor (VEGF) and prevents the interaction of VEGF to its receptors (Flt-1 and KDR) on the surface of endothelial cells. The interaction of VEGF with its receptors leads to endothelial cell proliferation and new blood vessel formation in

*in vitro* models of angiogenesis. Administration of bevacizumab to xenotransplant models of colon cancer in nude (athymic) mice caused reduction of microvascular growth and inhibition of metastatic disease progression.

*Formulations:*
Avastin: Intravenous solution: 100 mg/4 mL (4 mL); 400 mg/16 mL (16 mL)

*FDA Approved Indications:*
Avastin is a VEGF-specific angiogenesis inhibitor/solution for intravenous infusion indicated for the treatment of:

- Metastatic colorectal cancer, with intravenous 5-fluorouracil–based chemotherapy for first- or second-line treatment.*
- Metastatic colorectal cancer, with fluoropyrimidine- irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line Avastin containing regimen.
- Non-squamous non-small cell lung cancer, with carboplatin and paclitaxel for first line treatment of unresectable, locally advanced, recurrent or metastatic disease.
- Glioblastoma, as a single agent for adult patients with progressive disease following prior therapy. Effectiveness based on improvement in objective response rate. No data available demonstrating improvement in disease-related symptoms or survival with Avastin.
- Metastatic renal cell carcinoma with interferon alfa.
- Cervical cancer, in combination with paclitaxel and cisplatin or paclitaxel and topotecan in persistent, recurrent, or metastatic disease.
- Platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, in combination with paclitaxel, pegylated liposomal doxorubicin or topotecan.
- Platinum-sensitive recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer, in combination with carboplatin and paclitaxel or in combination with carboplatin and gemcitabine, followed by Avastin as a single agent.

*Limitation of use: Avastin is not indicated for adjuvant treatment of colon cancer.

**Appendices**
**Appendix A: Abbreviation Key**
5-FU/LV: fluorouracil, leucovorin
5-FU: fluorouracil
CapeOX: capecitabine, oxaliplatin
FOLFIRI: fluorouracil, leucovorin, irinotecan
FOLFOX: fluorouracil, leucovorin, oxaliplatin
FOLFOXIRI: fluorouracil, leucovorin, oxaliplatin, irinotecan
VEGF: vascular endothelial growth factor

**Coding Implications**
Codes referenced in this clinical policy are for informational purposes only. Inclusion or exclusion of any codes does not guarantee coverage. Providers should reference the most up-to-

date sources of professional coding guidance prior to the submission of claims for reimbursement of covered services.

| HCPCS Codes | Description |
|---|---|
| J9035 | Injection, bevacizumab, 10 mg |
| C9257 | Injection, bevacizumab, 0.25 mg |

**ICD-10-CM Diagnosis Codes that Support Coverage Criteria**
The following is a list of diagnosis codes that support coverage for the applicable covered procedure code(s).

| ICD-10-CM Code | Description |
|---|---|
| A18.53 | Tuberculosis chorioretinitis |
| C17.0 – C17.9 | Malignant neoplasm of small intestine |
| C18.0 – C18.9 | Malignant neoplasm of colon |
| C19 | Malignant neoplasm of rectosigmoid junction |
| C20 | Malignant neoplasm of rectum |
| C34.00 – C34.02 | Malignant neoplasm of main bronchus |
| C34.10 – C34.12 | Malignant neoplasm of upper lobe, bronchus or lung |
| C34.2 | Malignant neoplasm of middle lobe, bronchus or lung |
| C34.30 – C34.32 | Malignant neoplasm of lower lobe, bronchus or lung |
| C34.80 – C34.82 | Malignant neoplasm of overlapping sites of bronchus and lung |
| C34.90 – C34.92 | Malignant neoplasm of unspecified part of bronchus or lung |
| C48.0 – C48.8 | Malignant neoplasm of retroperitoneum and peritoneum |
| C49.0 – C49.9 | Malignant neoplasm of other connective and soft tissue |
| C50.01 – C50.929 | Malignant neoplasm of breast |
| C53.0 – C53.9 | Malignant neoplasm of cervix uteri |
| C54.0 – C55 | Malignant neoplasm of corpus uteri |
| C56.1 – C56.9 | Malignant neoplasm of ovary |
| C57.0 – C57.9 | Malignant neoplasm of other and unspecified female genital organs |
| C64.1 – C64.9 | Malignant neoplasm of kidney, except renal pelvis |
| C65.1 – C65.9 | Malignant neoplasm of renal pelvis |
| C70.0 – C70.9 | Malignant neoplasm of meninges |
| C71.0 – C71.9 | Malignant neoplasm of brain |
| C72.0 – C72.9 | Malignant of spinal cord, cranial neoplasm nerves and other parts of central nervous system |
| E08.311, E08.3211 – E08.3219, E08.3311 – E08.3319, E08.3411 – E08.3419, E08.3511 – E08.3519 | Diabetes mellitus due to underlying condition with diabetic retinopathy with macular edema |
| E09.311, | Drug or chemical induced diabetes mellitus with diabetic retinopathy with macular edema |

| ICD-10-CM Code | Description |
|---|---|
| E09.3211 – E09.3219, E09.3311 – E09.3319, E09.3411 – E09.3419, E09.3511 – E093519 | |
| E10.311, E10.3211 – E10.3219, E10.3311 – E10.3319, E10.3411 – E10.3419, E10.3511 – E10.3519 | Type 1 diabetes mellitus with diabetic retinopathy with macular edema |
| E11.311, E11.3211 – E11.3219, E11.3311 – E11.3319, E11.3411 – E11.3419, E11.3511 – E11.3519 | Type 2 diabetes mellitus with diabetic retinopathy with macular edema |
| E13.311, E13.3211 – E13.3219, E13.3311 – E13.3319, E13.3411 – E13.3419, E13.3511 – E13.3519 | Other specified diabetes mellitus with diabetic retinopathy with macular edema |
| H16.401 – H16.449 | Corneal neovascularization |
| H30.001 – H30.049 | Focal chorioretinal inflammation |
| H30.101 – H30.139 | Disseminated chorioretinal inflammation |
| H30.891 – H30.899 | Other chorioretinal inflammations |
| H30.90 – H30.93 | Unspecified chorioretinal inflammations |
| H32 | Chorioretinal disorders in diseases classified elsewhere |
| H34.8110 – H 34.8192 | Central retinal vein occlusion |
| H34.8310 – H34.8392 | Tributary (branch) retinal vein occlusion |
| H35.051 – H35.059 | Retinal neovascularization, unspecified |
| H35.141 – H35.169 | Retinopathy of prematurity, stages 3 through 5 |
| H35.3210 – H35.3293 | Exudative age-related macular degeneration |
| H35.33 | Angioid streaks of macula |
| H35.81 | Retinal edema |
| H40.50X0-H40.53X4 | Glaucoma secondary to other eye disorders [associated with vascular disorders of eye] |
| H44.20-H44.23 | Degenerative myopia |
| Z85.038 | Personal history of other malignant neoplasm of large intestine |
| Z85.048 | Personal history of other malignant neoplasm of rectum, rectosigmoid junction, and anus |
| Z85.068 | Personal history of other malignant neoplasm of small intestine |
| Z85.118 | Personal history of other malignant neoplasm of bronchus and lung |
| Z85.3 | Personal history of malignant neoplasm of breast |
| Z85.41 | Personal history of malignant neoplasm of cervix uteri |
| Z85.42 | Personal history of malignant neoplasm of other parts of uterus |

| ICD-10-CM Code | Description |
|---|---|
| Z85.43 | Personal history of malignant neoplasm of ovary |
| Z85.44 | Personal history of malignant neoplasm of other female genital organs |
| Z85.528 | Personal history of other malignant neoplasm of kidney |
| Z85.53 | Personal history of malignant neoplasm of renal pelvis |
| Z85.841 | Personal history of malignant neoplasm of brain |
| Z85.848 | Personal history of malignant neoplasm of other parts of nervous tissue |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| Reviewed with no clinical changes | 12/12 | 12/12 |
| Updated background, safety profile and contraindications | 02/14 | 03/14 |
| Added cervical cancer indication<br>Updated criteria per NCC guidelines for monotherapy or combination therapy and first line or maintenance therapy | 11/14 | 11/14 |
| Converted criteria into bullet points and changed to new policy template<br>Edited FDA-approved indications in section I to correspond to PI – all indications are limited to adults; added ovarian cancer;<br>Limited compendial indications to cancer type – all compendial indications are in section II<br>Added HCPCS and ICD-10 codes<br>Policy arranged in disease specific criteria sets<br>Added ocular indications as previously approved from CP.PHAR.38 | 10/15 | 11/15 |
| CP.PHAR.93.Avastin policy converted to new template; incorporates Avastin content from CP.PHAR.39 AMD Retinal Disorder Treatments.<br>Added age and max dose; monotherapy defined as “other anti-VEGF drugs;” removed requests for documentation.<br>References: removed 2008 Genentech letter regarding infections correlating with Avastin intravitreal use as it is no longer available. | 03/16 | 09/16 |
| Updated coding. Updated disclaimer language. | 09/16 | 09/16 |
| New FDA labeled indication added: Platinum-sensitive epithelial ovarian, fallopian tube, or primary peritoneal cancer. Doses removed. Under renal cell carcinoma, FDA approved use, added 2a/2b subtypes to interferon alpha. Safety criteria limited to black box warnings precluding initiation of therapy.Off-label ocular use is edited to follow supported uses in Micromedex and Clinical Pharmacology (i.e., AMD secondary to choroidal neovascularization, macular edema secondary to branch/central retinal vein occlusion or diabetes, choroidal retinal neovascularization secondary to pathologic myopia or angioid streaks, diabetic retinopathy, retinopathy of prematurity). Choroidal neovascularization associated with no known cause or with inflammation or ocular histoplasmosis syndrome is removed but may be requested under the Global Biopharm policy. Approval duration | 03/17 | 04/17 |

| Reviews, Revisions, and Approvals | Date | Approval Date |
|---|---|---|
| lengthened to 6 and 12 months. Added ICD-10 appropriate code ranges for eye conditions that now have a new 6th or 7th digit indicating the specific eye. | | |

**References**

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15. Diabetic retinopathy preferred practice pattern guidelines. American Academy of Ophthalmology; 2016. Available at www.aao.org/ppp. Accessed March 23, 2017.

**Important Reminder**

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of

physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. "Health Plan" means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan's affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

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**Note: For Medicaid members**, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

**Note: For Medicare members,** to ensure consistency with the Medicare National Coverage Determinations (NCD) and Local Coverage Determinations (LCD), all applicable NCDs, LCDs, and Medicare Coverage Articles should be reviewed prior to applying the criteria set forth in this clinical policy. Refer to the CMS website at http://www.cms.gov for additional information.