

POLICY Document for AVASTIN (bevacizumab)

The overall objective of this policy is to support the appropriate and cost effective use of the medication. This document provides specific information to each section of the overall policy.

Section 1: Clinical Criteria

- Policy information specific to the clinical appropriateness for the medication

Section 2: Oncology Clinical Policy

- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Clinical Criteria

SPECIALTY GUIDELINE MANAGEMENT

AVASTIN (bevacizumab)

POLICY

I. INDICATIONS

The indications below including FDA-approved indications and compendial uses are considered a covered benefit provided that all the approval criteria are met and the member has no exclusions to the prescribed therapy.

A. FDA-Approved Indications

1. Metastatic colorectal cancer (mCRC)
 - a. Avastin in combination with intravenous fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer.
 - b. Avastin in combination with fluoropyrimidine-irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy, is indicated for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab-containing regimen.
2. First-line non-squamous non-small cell lung cancer (NSCLC)

Avastin in combination with carboplatin and paclitaxel, is indicated for the first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer.
3. Recurrent glioblastoma (RGM)

Avastin is indicated for the treatment of recurrent glioblastoma in adults.
4. Metastatic renal cell carcinoma (mRCC)

Avastin in combination with interferon alfa, is indicated for the treatment of metastatic renal cell carcinoma.
5. Persistent, recurrent, or metastatic cervical cancer
Avastin in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer.
6. Epithelial ovarian, fallopian tube, or primary peritoneal cancer
 - a. Avastin, in combination with carboplatin and paclitaxel, followed by Avastin as a single agent, is indicated for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection.

- b. Avastin, in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, is indicated for the treatment of patients with platinum-resistant recurrent epithelial ovarian, fallopian tube or primary peritoneal cancer who received no more than 2 prior chemotherapy regimens.
- c. Avastin, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Avastin as a single agent, is indicated for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

B. Compendial Uses

1. Breast cancer for recurrent or stage IV (M1) human epidermal growth factor receptor 2 (HER2)-negative disease
2. Central nervous system (CNS) cancers
 - a. Low-grade (WHO Grade II) infiltrative supratentorial astrocytoma/oligodendroglioma
 - b. Intracranial and spinal ependymoma (excluding subependymoma)
 - c. Anaplastic gliomas
 - d. Medulloblastoma
 - e. Primary central nervous system lymphoma
 - f. Meningiomas
 - g. Limited and extensive brain metastases
 - h. Leptomeningeal metastases
 - i. Metastatic spine tumors
3. Malignant pleural mesothelioma
4. Ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer
 - a. Carcinosarcoma (malignant mixed Müllerian tumors)
 - b. Clear cell carcinoma
 - c. Mucinous carcinoma
 - d. Grade 1 endometrioid carcinoma
 - e. Low-grade serous carcinoma
 - f. Ovarian borderline epithelial tumors (low malignant potential) with invasive implants
 - g. Malignant sex cord-stromal tumors
5. Soft tissue sarcoma
 - a. Angiosarcoma
 - b. Solitary fibrous tumor/Hemangiopericytoma
6. AIDS-related Kaposi sarcoma
7. Uterine/Endometrial cancer
8. Vulvar cancer
9. Peritoneal mesothelioma
10. Pericardial mesothelioma
11. Tunica vaginalis testis mesothelioma
12. Small bowel adenocarcinoma
13. Appendiceal carcinoma
14. Anal adenocarcinoma
15. Ophthalmic disorders
 - a. Diabetic macular edema
 - b. Neovascular (wet) age-related macular degeneration (AMD)
 - c. Macular edema following retinal vein occlusion (RVO)
 - d. Proliferative diabetic retinopathy
 - e. Choroidal neovascularization (CNV)
 - f. Neovascular glaucoma; adjunct
 - g. Retinopathy of prematurity
 - h. Polypoidal choroidal vasculopathy

All other indications are considered experimental/investigational and not medically necessary.

II. CRITERIA FOR INITIAL APPROVAL

Avastin 1891-A SGM_NCCN_P2020.docx
49891A FNL3 Oncology Clinical Policy.docx

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A. Ophthalmic disorders

Authorization of 6 months may be granted for treatment of the following retinal disorders:

1. Diabetic macular edema
2. Neovascular (wet) age-related macular degeneration
3. Macular edema following retinal vein occlusion
4. Proliferative diabetic retinopathy
5. Choroidal neovascularization (including myopic choroidal neovascularization, angioid streaks, choroiditis [including choroiditis secondary to ocular histoplasmosis], idiopathic degenerative myopia, retinal dystrophies, rubeosis iridis, pseudoxanthoma elasticum, and trauma)
6. Neovascular glaucoma
7. Retinopathy of prematurity
8. Polypoidal choroidal vasculopathy

B. Colorectal cancer (CRC)

Authorization of 12 months may be granted for treatment of colorectal cancer, including small bowel adenocarcinoma, appendiceal carcinoma, and anal adenocarcinoma.

C. Non-small cell lung cancer (NSCLC)

Authorization of 12 months may be granted for treatment of recurrent, advanced, or metastatic non-squamous NSCLC.

D. CNS cancer

Authorization of 12 months may be granted for treatment of the following types of CNS cancer:

1. Glioblastoma
2. Intracranial and spinal ependymoma (excludes subependymoma)
3. Anaplastic gliomas
4. Low-grade (WHO Grade II) infiltrative supratentorial astrocytoma/oligodendroglioma
5. Medulloblastoma
6. Primary central nervous system lymphoma
7. Meningiomas
8. Limited and extensive brain metastases
9. Leptomeningeal metastases
10. Metastatic spine tumors

E. Ovarian cancer/Fallopian tube cancer/Primary peritoneal cancer

Authorization of 12 months may be granted for treatment of the following types of ovarian cancer, fallopian tube cancer, and primary peritoneal cancer:

1. Epithelial ovarian cancer, including:
 - i. Carcinosarcoma (malignant mixed Müllerian tumors)
 - ii. Clear cell carcinoma
 - iii. Mucinous carcinoma
 - iv. Grade 1 endometrioid carcinoma
 - v. Low-grade serous carcinoma
 - vi. Borderline epithelial tumors (low malignant potential) with invasive implants
 - vii. Malignant sex cord-stromal tumors
2. Fallopian tube cancer
3. Primary peritoneal cancer

F. Uterine/Endometrial cancer

Authorization of 12 months may be granted for treatment of progressive, advanced, or recurrent uterine cancer or endometrial cancer.

G. Cervical/Vaginal cancer

Authorization of 12 months may be granted for treatment of persistent, recurrent, or metastatic cervical or vaginal cancer.

H. Breast cancer

Authorization of 12 months may be granted for treatment of breast cancer.

I. Renal cell carcinoma

Authorization of 12 months may be granted for treatment of relapsed or metastatic renal cell carcinoma.

J. Soft tissue sarcoma

Angiosarcoma

Authorization of 12 months may be granted for treatment of angiosarcoma, as single agent therapy.

Solitary fibrous tumor/hemangiopericytoma

Authorization of 12 months may be granted for treatment of solitary fibrous tumor or hemangiopericytoma, in combination with temozolomide.

K. Malignant pleural mesothelioma

Authorization of 12 months may be granted for treatment of malignant pleural mesothelioma, in combination with pemetrexed and either cisplatin or carboplatin, followed by single agent maintenance therapy.

L. AIDS-related Kaposi sarcoma

Authorization of 12 months may be granted for treatment of AIDS-related Kaposi sarcoma.

M. Vulvar cancer

Authorization of 12 months may be granted for treatment of unresectable locally advanced, recurrent, or metastatic vulvar cancer.

N. Peritoneal mesothelioma

Authorization of 12 months may be granted for treatment of peritoneal mesothelioma.

O. Pericardial mesothelioma

Authorization of 12 months may be granted for treatment of pericardial mesothelioma.

P. Tunica vaginalis testis mesothelioma

Authorization of 12 months may be granted for treatment of tunica vaginalis testis mesothelioma.

III. CONTINUATION OF THERAPY

A. Ophthalmic disorders

For ophthalmic disorders, authorization of 12 months may be granted for continued treatment of an indication outlined in Section II for members who have demonstrated a positive clinical response to therapy (e.g., improvement or maintenance in best corrected visual acuity [BCVA] or visual field, or a reduction in the rate of vision decline or the risk of more severe vision loss).

B. All other indications

For all other indications, authorization of 12 months may be granted for continued treatment of an indication outlined in Section II for members who are experiencing a clinical benefit to therapy or who have not experienced an unacceptable toxicity.

Section 2: Oncology Clinical Policy

Oncology Clinical Policy

Program Description

The National Comprehensive Care Network® (NCCN®) is an alliance of leading cancer centers devoted to patient care, research and education dedicated to improving the quality, effectiveness and efficiency of cancer care so patients can live better lives.¹ It is comprised of oncology experts who convene regularly to establish the best treatments for patients. NCCN develops various resources for use by stakeholders in the health care delivery system. These resources include, but are not limited to, the NCCN Clinical Practice Guidelines in Oncology (NCCN Guidelines®), the NCCN Drugs & Biologics Compendium (NCCN Compendium®) and the NCCN Chemotherapy Order Templates (NCCN Templates®).

NCCN templates are based on NCCN Clinical Practice Guidelines and NCCN Compendium. The NCCN Compendium lists the appropriate drugs and biologics for specific cancers using U.S. Food and Drug Administration (FDA)-approved disease indications and specific NCCN panel recommendations. Each recommendation is supported by a level of evidence category.

NCCN Categories of Evidence and Consensus²

- Category 1: Based on high-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2A: Based on lower-level evidence, there is uniform NCCN consensus that the intervention is appropriate.
- Category 2B: Based on lower-level evidence, there is NCCN consensus that the intervention is appropriate.
- Category 3: Based any level of evidence, there is major NCCN disagreement that the intervention is appropriate.

Policy for Regimen Prior Authorization

A regimen prior authorization allows submission of a single prior authorization request for all oncology drugs or biologics within an NCCN template that require prior authorization.

This policy provides coverage of a regimen review when *all* of the following criteria are met:

- a. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal: <https://provider.carefirst.com/providers/home.page>
- b. If the prior authorization request is submitted via phone or fax, each drug or biologic will need to be submitted and reviewed as a separate prior authorization request for review with drug-specific criteria.
2. The prior authorization review is requested for an oncology drug or biologic that requires prior authorization on the medical benefit.
3. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include breast, lung, colon and rectal cancer.
4. The member is eligible for regimen review.

In addition, the following criteria must be met for approval:

1. The requested regimen for the drug(s) or biologic(s) and indication is consistent with an NCCN recommendation with a level of evidence category of 1 or 2A.
2. The NCCN template must be accepted by the provider without modification.

Authorizations may be granted for 12 months.

Further review may be indicated where the above criteria are not met.

Continuation of Therapy

To submit a request for continuation of therapy, a new regimen prior authorization review must be requested. Upon template selection, the template must be modified to include the appropriate therapies being used for maintenance treatment. The regimen request will be submitted for further review.

Dosage and Administration

Approvals may be subject to dosing limits in accordance with FDA-approved labeling, accepted compendia and/or evidence-based practice guidelines.

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