POLICY Document for AVASTIN (bevacizumab)

The overall objective of this policy is to support the appropriate and cost-effective use of the medication, specific to use of preferred medication options, and overall, clinically appropriate use. This document provides specific information to both sections of the overall policy.

Section 1: Preferred Product
- Policy information specific to preferred medications

Section 2: Clinical Criteria
- Policy information specific to the clinical appropriateness for the medication

Section 3: Oncology Clinical Policy
- Policy information specific to regimen review per NCCN Guidelines.

Section 1: Preferred Product

CAREFIRST: EXCEPTIONS CRITERIA
BEVACIZUMAB-ONCOLOGY PRODUCTS

PREFERRED PRODUCTS: MVASI AND ZIRABEV

Client Requested: The intent of the criteria is to ensure that patients follow selection elements as established by CareFirst.

POLICY
This policy informs prescribers of preferred products and provides an exception process for targeted products through prior authorization.

I. PLAN DESIGN SUMMARY

This program applies to the bevacizumab products specified in this policy when the requested drug will be used to treat cancer. Coverage for targeted product is provided based on clinical circumstances that would exclude the use of the preferred products and may be based on previous use of a product. The coverage review process will ascertain situations where a clinical exception can be made. This program applies to all members requesting treatment with a targeted product.

Each referral is reviewed based on all utilization management (UM) programs implemented for the client.

Table. Bevacizumab-Oncology Products

	Product(s)
Preferred*	• **Mvasi** (bevacizumab-awwb) • **Zirabev** (bevacizumab-bvzr)
Targeted	• **Avastin** (bevacizumab) • **Alymsys** (bevacizumab-maly) • **Vegzelma** (bevacizumab-adcd)

II. EXCEPTION CRITERIA

This program applies to members requesting treatment for cancer where the indication is FDA-approved for the preferred products.

Coverage for the targeted product is provided when member has a documented inadequate response, contraindication, or intolerable adverse event to both preferred products and the adverse event was not an expected adverse event attributed to the active ingredient as described in the prescribing information (i.e., known adverse reaction for both the reference product and biosimilar products).

Section 2: Clinical Criteria

Specialty Guideline Management bevacizumab

Products Referenced by this Document

Drugs that are listed in the following table include both brand and generic and all dosage forms and strengths unless otherwise stated. Over-the-counter (OTC) products are not included unless otherwise stated.

Brand Name	Generic Name
Avastin	bevacizumab
Alymsys	bevacizumab-maly
Avzivi	bevacizumab-tnjn
Mvasi	bevacizumab-awwb
Vegzelma	bevacizumab-adcd
Zirabev	bevacizumab-bvzr

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.

FDA-Approved Indications[1-6]

Metastatic Colorectal Cancer (mCRC)

- Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with intravenous fluorouracil-based chemotherapy, is indicated for the first- or second-line treatment of patients with metastatic colorectal cancer.
- Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, 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 product-containing regimen.

First-Line Non-Squamous Non-Small Cell Lung Cancer (NSCLC)

Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, 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.

Recurrent Glioblastoma (RGM)

Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, is indicated for the treatment of recurrent glioblastoma in adults.

Metastatic Renal Cell Carcinoma (mRCC)

Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with interferon alfa, is indicated for the treatment of metastatic renal cell carcinoma.

Persistent, Recurrent, or Metastatic Cervical Cancer

Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, in combination with paclitaxel and cisplatin or paclitaxel and topotecan, is indicated for the treatment of patients with persistent, recurrent, or metastatic cervical cancer.

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

- Avastin, Mvasi, Vegzelma or Zirabev, in combination with carboplatin and paclitaxel, followed by Avastin, Mvasi, Vegzelma or Zirabev 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.
- Avastin, Alymsys, Avzivi, Mvasi, Vegzelma or Zirabev, 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.
- Avastin, Mvasi, Vegzelma or Zirabev, in combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by Avastin, Mvasi, Vegzelma or Zirabev as a single agent, is indicated for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer.

Hepatocellular Carcinoma

Avastin, in combination with atezolizumab, is indicated for the treatment of patients with unresectable or metastatic hepatocellular carcinoma (HCC) who have not received prior systemic therapy.

CVS/caremark

Compendial Uses[7-30]

- Central Nervous System (CNS) Cancers
  - Circumscribed glioma
  - Diffuse high grade and high grade gliomas
  - Glioblastoma
  - IDH mutant astrocytoma (WHO Grade 2, 3, or 4)
  - Oligodendroglioma (WHO Grade 2 or 3)
  - Intracranial and Spinal Ependymoma (excluding subependymoma)
  - Medulloblastoma
  - Primary Central Nervous System Lymphoma
  - Meningiomas
  - Limited and Extensive Brain Metastases
  - Metastatic Spine Tumors
  - Primary Spinal Cord Tumors
- Pleural Mesothelioma, Peritoneal Mesothelioma, Pericardial Mesothelioma, Tunica Vaginalis Testis Mesothelioma
- Ovarian Cancer, Fallopian Tube Cancer, Primary Peritoneal Cancer
- Soft Tissue Sarcoma
  - Angiosarcoma
  - Solitary Fibrous Tumor/Hemangiopericytoma
- Uterine Neoplasms/Endometrial Carcinoma
- Vulvar Carcinoma
- Vaginal Cancer
- Cervical Cancer
- Small Bowel Adenocarcinoma
- Ampullary Adenocarcinoma
- Appendiceal Adenocarcinoma
- Anal Adenocarcinoma
- Renal Cell Carcinoma
- Hepatocellular Carcinoma
- Ophthalmic Disorders
  - Diabetic Macular Edema
  - Neovascular (wet) Age-Related Macular Degeneration
  - Macular Edema following Retinal Vein Occlusion
  - Proliferative Diabetic Retinopathy
  - Choroidal Neovascularization
  - Neovascular Glaucoma
  - Retinopathy of Prematurity
  - Polypoidal Choroidal Vasculopathy

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

CVS/caremark

Coverage Criteria

Ophthalmic Disorders[8-25,29]

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

- Diabetic Macular Edema
- Neovascular (wet) Age-Related Macular Degeneration
- Macular Edema following Retinal Vein Occlusion
- Proliferative Diabetic Retinopathy
- 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)
- Neovascular Glaucoma
- Retinopathy of Prematurity
- Polypoidal Choroidal Vasculopathy

Colorectal Cancer (CRC)[1-8,26,27,28]

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

Small Bowel Adenocarcinoma[7]

Authorization of 12 months may be granted for treatment of small bowel adenocarcinoma.

Ampullary Adenocarcinoma[7]

Authorization of 12 months may be granted for treatment of intestinal-type ampullary adenocarcinoma that is progressive, unresectable, or metastatic.

Non-Small Cell Lung Cancer (NSCLC)[1-7]

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

CNS Cancer[1-7]

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

- Circumscribed glioma
- Diffuse high grade and high grade gliomas
- Glioblastoma
- IDH mutant astrocytoma (WHO Grade 2, 3 or 4)
- Oligodendroglioma (WHO Grade 2 or 3)
- Intracranial and Spinal Ependymoma (excludes subependymoma)
- Medulloblastoma

- Primary Central Nervous System Lymphoma
- Meningiomas
- Limited and Extensive Brain Metastases
- Metastatic Spine Tumors
- Primary Spinal Cord Tumors

Ovarian Cancer/Fallopian Tube Cancer/Primary Peritoneal Cancer[1-7]

Authorization of 12 months may be granted for treatment of epithelial ovarian cancer, fallopian tube cancer, primary peritoneal cancer, and malignant sex cord stromal tumors.

Uterine Neoplasms/Endometrial Carcinoma[7,29]

Authorization of 12 months may be granted for treatment of progressive, persistent, recurrent, or metastatic uterine neoplasms or endometrial carcinoma.

Cervical Cancer[1-7]

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

Vaginal Cancer[7]

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

Renal Cell Carcinoma[1-7]

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

Soft Tissue Sarcoma[7,30]

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

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

Mesothelioma[7,8]

Authorization of 12 months may be granted for treatment of pleural mesothelioma, peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma when any of the following criteria are met:

- As first-line therapy in combination with pemetrexed and either cisplatin or carboplatin, followed by single-agent maintenance bevacizumab
- As subsequent therapy in combination with pemetrexed and either cisplatin or carboplatin if immunotherapy was administered as first-line treatment

Authorization of 12 months may be granted for treatment of peritoneal mesothelioma, pericardial mesothelioma, or tunica vaginalis testis mesothelioma when used in combination with atezolizumab as subsequent therapy.

Vulvar Carcinoma[7]

Authorization of 12 months may be granted for treatment of advanced, recurrent, or metastatic vulvar carcinoma, including squamous cell carcinoma and adenocarcinoma.

Hepatocellular Carcinoma[1,7]

Authorization of 12 months may be granted for treatment of unresectable or extrahepatic/metastatic hepatocellular carcinoma, when the requested medication will be used as initial treatment in combination with atezolizumab.

Authorization of 12 months may be granted for adjuvant treatment of operable hepatocellular carcinoma, when the member is at a high risk of recurrence and the requested medication will be used in combination with atezolizumab.

Continuation of Therapy

Ophthalmic Disorders

For ophthalmic disorders, authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Coverage Criteria section when the member has 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).

All Other Indications

For all other indications, authorization of 12 months may be granted for continued treatment in members requesting reauthorization for an indication listed in Coverage Criteria section when there is no evidence of unacceptable toxicity or disease progression while on the current regimen.

Section 3: Oncology Clinical Policy

PURPOSE

The purpose of this policy is to define the Novologix NCCN® Regimen Prior Authorization Program.

SCOPE

This policy applies to clients who have implemented the Novologix NCCN® Program as a part of their medical and/or pharmacy prior authorization solution.

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 Guidelines® and NCCN Compendium®. The NCCN Compendium lists the appropriate drugs and biologics as treatment options 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 Consensus[2]

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

POLICY

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.

PROCEDURE

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

1. Regimen prior authorization reviews, based on NCCN templates, are initiated through the provider portal.
   - 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.

3. The member is eligible for regimen review.
4. The indication is for a cancer that is eligible for regimen review. Currently, the cancer types in scope for regimen review include the following:

- Ampullary Adenocarcinoma
- Anal Carcinoma
- B-Cell Lymphomas
- Basal Cell Skin Cancer
- Biliary Tract Cancers
- Bone Cancer
- Breast Cancer
- Bladder Cancer
- Central Nervous System Cancers
- Cervical Cancer
- Chronic Lymphocytic Leukemia/Small Lymphocytic Lymphoma
- Chronic Myeloid leukemia
- Colon Cancer
- Dermatofibrosarcoma Protuberans
- Esophageal Cancer
- Gastric Cancer
- Gastrointestinal Stromal Tumors
- Gestational Trophoblastic Neoplasms
- Hairy Cell Leukemia
- Head and Neck Cancers
- Histiocytic Neoplasms
- Hodgkin Lymphoma
- Hepatocellular Carcinoma
- Kaposi Sarcoma
- Kidney Cancer
- Melanoma: Cutaneous
- Melanoma: Uveal
- Merkel Cell Carcinoma
- Mesothelioma: Peritoneal
- Mesothelioma: Pleural
- Multiple Myeloma
- Myelodysplastic Syndromes
- Myeloid/Lymphoid Neoplasms with Eosinophilia and Tyrosine Kinase Gene Fusions
- Myeloproliferative Neoplasms
- Neuroendocrine and Adrenal Tumors
- Non-Small Cell Lung Cancer
- Occult Primary
- Ovarian Cancer
- Pancreatic Cancer
- Penile Cancer
- Primary Cutaneous Lymphomas

- Prostate Cancer
- Rectal Cancer
- Small Bowl Adenocarcinoma
- Small Cell Lung Cancer
- Soft Tissue Sarcoma
- Squamous Cell Skin Cancer
- Systemic Mastocytosis
- Systemic Light Chain Amyloidosis
- T-Cell Lymphomas
- Testicular Cancer
- Thymomas and Thymic Carcinomas
- Thyroid Carcinoma
- Uterine Neoplasms
- Vaginal Cancer
- Vulvar Cancer
- Waldenström Macroglobulinemia / Lymphoplasmacytic Lymphoma
- Wilms Tumor (Nephroblastoma)

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.

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

Authorizations may be granted for 12 months or as medically required, based on the member's condition and provider's assessment.

Supportive Care: Myeloid Growth Factor Therapy

Granulocyte colony stimulating factors are recommended for primary prophylaxis based on the febrile neutropenia risk of the chemotherapy regimen. Febrile neutropenia risk levels vary by NCCN Chemotherapy Order template and are listed at the top of the template. Regimens associated with a high or intermediate risk of febrile neutropenia may include a granulocyte colony stimulating factor as part of the prior authorization.

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 evidence-based practice guidelines.

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