

Pharmacy Medical Necessity Guidelines: Avastin® (bevacizumab)

Effective: April 1, 2021

Prior Authorization Required	√	Type of Review – Care Management	
Not Covered		Type of Review – Clinical Review	
Pharmacy (RX) or Medical (MED) Benefit	MED / RX	Department to Review	PRECERT /MM
<p>These pharmacy medical necessity guidelines apply to the following:</p> <p>Commercial Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – large group plans <input checked="" type="checkbox"/> Tufts Health Plan Commercial products – small group and individual plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – large group plans <input checked="" type="checkbox"/> Tufts Health Freedom Plan products – small group plans • CareLinkSM – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization <p>Tufts Health Public Plans Products</p> <ul style="list-style-type: none"> <input checked="" type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product) <input checked="" type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans <input checked="" type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan 		<p>Fax Numbers:</p> <p>All plans except Tufts Health Public Plans PRECERT: 617.972.9409</p> <p>Tufts Health Public Plans MM: 888.415.9055</p>	

Note: This guideline does not apply to Medicare Members (includes dual eligible Members).

OVERVIEW

NOTE: This policy only applies to HCPCS code J9035 Injection, bevacizumab, 10 mg (See Codes section below). **This policy does not apply to the HCPCS code C9257 Injection, bevacizumab, 0.25 mg, which is commonly billed for the treatment of ophthalmic conditions, such as Neovascular (Wet) Age-Related Macular Degeneration (AMD), in the office setting.**

FOOD AND DRUG ADMINISTRATION-APPROVED INDICATIONS

Bevacizumab is a vascular endothelial growth factor inhibitor indicated for the treatment of the following types of cancers:

Epithelial Ovarian, Fallopian Tube, or Primary Peritoneal Cancer

- In combination with carboplatin and paclitaxel, followed by bevacizumab as a single agent, for the treatment of patients with stage III or IV epithelial ovarian, fallopian tube, or primary peritoneal cancer following initial surgical resection
- In combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan, 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
- In combination with carboplatin and paclitaxel, or with carboplatin and gemcitabine, followed by bevacizumab as a single agent, for the treatment of patients with platinum-sensitive recurrent epithelial ovarian, fallopian tube, or primary peritoneal cancer

First-line Non-squamous Non-Small Cell Lung Cancer

- In combination with carboplatin and paclitaxel, for first-line treatment of patients with unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer

Metastatic Colorectal Cancer

- In combination with intravenous fluorouracil-based chemotherapy, for first- or second-line treatment of patients with metastatic colorectal cancer
- In combination with fluoropyrimidine-irinotecan – or fluoropyrimidine-oxaliplatin-based chemotherapy, for second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line bevacizumab-containing regimen

Metastatic Renal Cell Carcinoma5

- In combination with interferon alfa, for the treatment of metastatic renal cell carcinoma

Persistent, Recurrent, or Metastatic Cervical Cancer

- In combination with paclitaxel and cisplatin or paclitaxel and topotecan, for the treatment of patients with persistent, recurrent, or metastatic cervical cancer

Recurrent Glioblastoma

- Treatment of recurrent glioblastoma in adults

Available bevacizumab biosimilars include Mvasi (bevacizumab-awwb) and Zirabev (bevacizumab-bvzr).

COVERAGE GUIDELINES

The plan may authorize the coverage of Avastin (bevacizumab) for Members, when all of the following criteria are met:

1. Documented previous failure of or clinical inappropriateness with a bevacizumab biosimilar

Off-label Use Coverage for Other Cancer Diagnoses

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provisions of the "Sullivan Law": (M.G.L. c.175, s.47K).

The plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a "Medically Accepted Indication" according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

Note: The plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s).

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, The plan will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless otherwise directed by the commissioner, and accept clinical documentation referenced in one of the other "Standard Reference Compendia" noted below or supported by clinical research that appears in a regular edition of a "Peer-Reviewed Medical Literature" noted below.

"Standard Reference Compendia"

1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs

"Peer Reviewed Medical Literature"

- American Journal of Medicine
- Annals of Internal Medicine
- Annals of Oncology
- Annals of Surgical Oncology
- Biology of Blood and Marrow Transplantation
- Blood
- Bone Marrow Transplantation
- British Journal of Cancer
- British Journal of Hematology
- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- Gynecologic Oncology
- International Journal of Radiation, Oncology, Biology, and Physics
- The Journal of the American Medical Association
- Journal of Clinical Oncology
- Journal of the National Cancer Institute
- Journal of the National Comprehensive Cancer Network (NCCN)
- Journal of Urology
- Lancet
- Lancet Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

When the plan evaluates the evidence in published, peer-reviewed medical literature, consideration will be given to the following:

1. Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy regimen is adequately represented in the published evidence.

3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
4. Whether the study is appropriate to address the clinical question.
 - a. whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question (e.g., in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover);
 - b. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,
 - c. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

LIMITATIONS

- Coverage of Avastin (bevacizumab) will be authorized for any FDA-approved indication that available biosimilars do not share.
- Coverage of HCPCS code J9035 Injection, bevacizumab, 10 mg (Avastin) will not be authorized for the treatment or management of ophthalmic conditions.”
- Documentation of any previous use of Avastin (bevacizumab) does not qualify as a clinically appropriate reason to not prescribe biosimilars.
- Authorizations will be provided for 12 months.

CODES

The following HCPCS/CPT code(s) are:

Code	Description
J9035	Injection, bevacizumab, 10 mg

REFERENCES

1. Avastin (bevacizumab) [prescribing information]. South San Francisco, CA: Genentech, Inc.; June 2019.
2. Mvasi (bevacizumab-awwb) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; June 2019.
3. Zirabev (bevacizumab-bvzr) [prescribing information]. New York, NY: Pfizer Inc.; June 2019.

APPROVAL HISTORY

January 14, 2020: Reviewed by Pharmacy & Therapeutics Committee.

Subsequent endorsement date(s) and changes made:

1. April 14, 2020: Delayed the implementation date of the Medical Necessity Guideline to July 1, 2020.
2. July 14, 2020: Delayed the implementation date of the Medical Necessity Guideline to October 1, 2020.
3. January 12, 2021: Effective April 1, 2021, added the clarification Limitation will be updated to “Coverage of HCPCS code J9035 Injection, bevacizumab, 10 mg (Avastin) will not be authorized for the treatment or management of ophthalmic conditions.”

BACKGROUND, PRODUCT AND DISCLAIMER INFORMATION

Pharmacy Medical Necessity Guidelines have been developed for determining coverage for plan benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. The plan makes coverage decisions on a case-by-case basis considering the individual member's health care needs. Pharmacy Medical Necessity Guidelines are developed for selected therapeutic classes or drugs found to be safe, but proven to be effective in a limited, defined population of patients or clinical circumstances. They include concise clinical coverage criteria based on current literature review, consultation with practicing physicians in the service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. The plan revises and updates Pharmacy Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests needed revisions.

For self-insured plans, coverage may vary depending on the terms of the benefit document. If a discrepancy exists between a Pharmacy Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern.

Treating providers are solely responsible for the medical advice and treatment of members. The use of this policy is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of

benefits, referral/authorization and utilization management guidelines when applicable, and adherence to plan policies and procedures and claims editing logic.