Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines

Medical Benefit Drugs

Bevacizumab Products: Avastin (bevacizumab), Alymsys (bevacizumab-maly), Vegzelma (bevacizumab-abcd)

Effective: September 10, 2024

Guideline Type	☒ Prior Authorization ☐ Non-Formulary ☐ Step-Therapy ☐ Administrative

Applies to:

Commercial Products

☐ Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988

☒ Tufts Health Plan Commercial products; Fax 617-673-0988

CareLink℠ – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization

Public Plans Products

☒ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988

☒ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0939

☒ Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0939

☐ Tufts Health One Care* – A Medicare-Medicaid Plan (a dual eligible product); Fax 617-673-0956

*The MNG applies to Tufts Health One Care members unless a less restrictive LCD or NCD exists.

Senior Products

☐ Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956

☐ Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956

☐ Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956

☐ Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956

Note: While you may not be the provider responsible for obtaining prior authorization, as a condition of payment you will need to ensure that prior authorization has been obtained.

Overview

Food and Drug Administration (FDA)-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 Carcinoma
- 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

Mvasi (bevacizumab- awwb) and Zirabev (bevacizumab- bvzr) are preferred bevacizumab products and do not require prior authorization.

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.**

NOTE: Providers and Members enrolled with Harvard Pilgrim Health Care may reference the HPHC/OncoHealth guideline for coverage of oncology-related indications, located at https://oncohealth.us/medicalpolicies/harvardpilgrim/

Clinical Guideline Coverage Criteria

The plan may authorize coverage for Avastin, Alymsys, or Vegzelma when the following clinical criteria are met:

1. Documented previous failure of or clinical inappropriateness of treatment with Mvasi or Zirabev

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 provision 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 Acceptable 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 treatment 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
- 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

- British Medical Journal
- Cancer
- Clinical Cancer Research
- Drugs
- European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology)
- 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. appropriate to address the investigative question (for example, 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, Alymsys, or Vegzelma will be authorized for any FDA-approved indication that preferred bevacizumab 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, Alymsys, or Vegzelma does not qualify as a clinically appropriate reason to not prescribe biosimilars.
- Authorizations will be provided for 12 months.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9035	Injection, bevacizumab, 10 mg
Q5126	Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg
Q5129	Injection, bevacizumab-adcd (Vegzelma), biosimilar, 10 mg

References

1. Alymsys (bevacizumab-maly) [prescribing information]. Bridgewater, NJ; Amneal Pharmaceuticals, LLC. April 2022.
2. Avastin (bevacizumab) [prescribing information]. South San Francisco, CA: Genentech, Inc.; November 2021.
3. Mvasi (bevacizumab-awwb) [prescribing information]. Thousand Oaks, CA: Amgen Inc.; November 2021.
4. Vegzelma (bevacizumab-abcd) [prescribing information]. Incheon, Republic of Korea: Celltrion, Inc.; September 2022.
5. Zirabev (bevacizumab-bvzr) [prescribing information]. New York, NY: Pfizer Inc.; May 2021.

Approval And Revision History

December 13, 2022: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees
- December 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)
- December 2022 added Vegzelma as non-preferred Bevacizumab oncology product effective February 1, 2023

- Administrative update: March 2023 added Medical Benefit Drugs to title and updated MATogether and RITogether fax numbers to 617-673-0939
- Coding update per HCPCS level II quarterly release. Effective date April 1, 2023, the following HCPCS codes have been added: Q5129
- October 10, 2023: Updated criteria to "Documented previous failure of or clinical inappropriateness of treatment with Mvasi or Zirabev.” Coverage for Tufts Health Together applies to Medical Necessity Guideline (effective 1/1/2024).
- September 10, 2024: No changes (eff 9/10/24).
- September 2024: Administrative Update: Updated from Tufts Unify to Tufts One Care to reflect name change.

Background, Product and Disclaimer Information

Medical Necessity Guidelines are developed to determine coverage for benefits and are published to provide a better understanding of the basis upon which coverage decisions are made. We make coverage decisions using these guidelines, along with the Member’s benefit document, and in coordination with the Member’s physician(s) on a case-by-case basis considering the individual Member's health care needs.

Medical Necessity Guidelines are developed for selected therapeutic or diagnostic services found to be safe and proven 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 our service area who are medical experts in the particular field, FDA and other government agency policies, and standards adopted by national accreditation organizations. We revise and update 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 Medical Necessity Guideline and a self-insured Member’s benefit document, the provisions of the benefit document will govern. For Tufts Health Together (Medicaid), coverage may be available beyond these guidelines for pediatric members under age 21 under the Early and Periodic Screening, Diagnostic and Treatment (EPSDT) benefits of the plan in accordance with 130 CMR 450.140 and 130 CMR 447.000, and with prior authorization.

Treating providers are solely responsible for the medical advice and treatment of Members. The use of this guideline is not a guarantee of payment or a final prediction of how specific claim(s) will be adjudicated. Claims payment is subject to eligibility and benefits on the date of service, coordination of benefits, referral/authorization, utilization management guidelines when applicable, and adherence to plan policies, plan procedures, and claims editing logic.