

Effective: February 1, 2023

<p><b>Prior Authorization Required</b> If <b>REQUIRED</b>, submit supporting clinical documentation pertinent to service request.</p>	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
<p><b>Applies to:</b></p> <p><b>Commercial Products</b></p> <p><input type="checkbox"/> Harvard Pilgrim Health Care Commercial products; Fax 617-673-0988</p> <p><input type="checkbox"/> Tufts Health Plan Commercial products; Fax 617-673-0988 CareLink<sup>SM</sup> – Refer to CareLink Procedures, Services and Items Requiring Prior Authorization</p> <p><b>Public Plans Products</b></p> <p><input type="checkbox"/> Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product); Fax 617-673-0988</p> <p><input type="checkbox"/> Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans; Fax 617-673-0988</p> <p><input type="checkbox"/> Tufts Health RITogether – A Rhode Island Medicaid Plan; Fax 617-673-0988</p> <p><input type="checkbox"/> Tufts Health Unify* – OneCare Plan (a dual-eligible product); Fax 617-673-0956 *The MNG applies to Tufts Health Unify members unless a less restrictive LCD or NCD exists.</p> <p><b>Senior Products</b></p> <p><input checked="" type="checkbox"/> Harvard Pilgrim Health Care Stride Medicare Advantage; Fax 617-673-0956</p> <p><input type="checkbox"/> Tufts Health Plan Senior Care Options (SCO), (a dual-eligible product); Fax 617-673-0956</p> <p><input type="checkbox"/> Tufts Medicare Preferred HMO, (a Medicare Advantage product); Fax 617-673-0956</p> <p><input type="checkbox"/> Tufts Medicare Preferred PPO, (a Medicare Advantage product); Fax 617-673-0956</p>	

**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

Some medically administered Part B drugs may have additional requirements or limits on coverage. These requirements and limits may include step therapy. This is when we require you to first try certain preferred drugs to treat your medical condition before we will cover another non-preferred drug for that condition.

This policy supplements Medicare Local Coverage Determinations (LCDs) and National Coverage Determinations (NCDs) for the purpose of determining coverage under Medicare Part B medical benefits and applies a step therapy for the following drugs/products.

A Member cannot be required under this policy to change a current drug/product. For the purposes of this policy, a current drug/product means the member has a paid claim for the drug/product within the past 365 days or there is clinical documentation of the member utilizing the non-preferred drug. For example, a new plan Member currently using a particular drug/product will not be required to switch to the preferred drug/product upon enrollment. Similarly, an existing member currently using a particular drug/product will not be required to change drug/products in the event this policy is updated.

This policy applies a step therapy for the following drugs/products. This list indicates the common uses for which the drug is prescribed. This list can change from time to time.

Drug Class	Non-preferred Product(s)	Preferred Product(s)
<b>Bendamustine HCl Injection</b>	Treanda	Bendeka Belrapzo

<b>Bevacizumab – oncology</b>	Avastin Alymsys Vegzelma	Mvasi Zirabev
<b>Leucovorin / LEVOleucovorin Injection</b>	Fusilev Khapzory	leucovorin injection
<b>Neutropenia Colony Stimulating Agents – long acting</b>	Fylnetra Nyvepria Udenyca Ziextenzo	Fulphila Neulasta
<b>Neutropenia Colony Stimulating Agents – short acting</b>	Granix Leukine Neupogen Nivestym Releuko	Zarxio
<b>Rituximab</b>	Rituxan Rituxan Hycela Riabni	Ruxience Truxima
<b>Trastuzumab</b>	Herceptin Herceptin Hylecta Herzuma Ontruzant	Kanjinti Ogivri Trazimera

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## Clinical Guideline Coverage Criteria

In addition to any LCD/NCD policies required by the Plan, a non-preferred product must satisfy the following criteria. If a provider administers a non-preferred product without obtaining prior authorization, Harvard Pilgrim Healthcare may deny claims for the non-preferred product.

1. Documentation of one (1) of the following:
  - a. History of use of at least one preferred product resulting in a substandard response to therapy  
**OR**
  - b. History of intolerance or adverse event to at least one preferred product  
**OR**
  - c. Rationale that the preferred product(s) is not clinically appropriate (Note: Convenience does not qualify as clinical rationale for inappropriateness of a preferred product)  
**OR**
  - d. Continuation of prior therapy with the requested non-preferred product within the past 365 days

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## Approval And Revision History

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

December 21, 2022: Reviewed by the Medical Policy Approval Committee (MPAC)

Subsequent changes:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees
- December 2022 added Vegzelma as non-preferred Bevacizumab oncology product effective February 1, 2023

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## 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.