Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:

Medical Benefit Drugs

OncoHealth Medicare Part B Step Therapy

Effective: July 1, 2024

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

Applies to:

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

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)
Antiemetics	Akynzeo Cinvanti Sustol	fosaprepitant granisetron ondansetron palonosetron Aloxi Emend
Bendamustine HCl Injection	Treanda Vivimusta	bendamustine Bendeka Belrapzo
Bevacizumab – oncology	Avastin Alymsys Vegzelma	Mvasi Zirabev
Bone Resorption Inhibitors	Prolia Xgeva	ibandronate pamidronate zoledronic acid
Leucovorin / LEVOleucovorin Injection	Fusilev Khapzory LEVOleucovorin	leucovorin injection
Neutropenia Colony Stimulating Agents – long acting	Fylnetra Nyvepria Rolvedon Ryzneuta Stimufend Udenyca Ziextenzo	Fulphila Neulasta
Neutropenia Colony Stimulating Agents – short acting	Granix Leukine Neupogen Nivestym Releuko	Zarxio
Rituximab	Rituxan Rituxan Hycela Riabni	Ruxience Truxima
Trastuzumab	Herceptin Herceptin Hylecta Hercessi Herzuma Ogivri Ontruzant	Kanjinti Trazimera

Clinical Guideline Coverage Criteria

In addition to any prior authorization requirements by the plan, a non-preferred product must satisfy the following criteria. If a provider administers a non-preferred product without obtaining prior authorization, the plan 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
    b. History of intolerance or adverse event to at least one preferred product
    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)
    d. Continuation of prior therapy with the requested non-preferred product within the past 365 days

Approval And Revision History

February 14, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent changes:

- February 15, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)
- 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
- March 2032 added Rolvedon and Stimufend as non-preferred Neutropenia Colony Stimulating Agents – long acting products effective April 1, 2023
- June 22, 2023: Added bendamustine and Vivimusta to the Medical Necessity Guideline (effective July 1, 2023)
- September 12, 2023: Added the following new Part B Step Therapy strategies: Antiemetics and Bone Resorption Inhibitors. Added generic LEVOleucovorin as a non-preferred agent. Ogivri moved to a non-preferred product (effective January 1, 2024).
- June 11, 2024: Added Ryzneuta and Hercessi to the Medical Necessity Guideline (effective July 1, 2024).
- June 2024: Joint Medical Policy and Health Care Services UM Committee review (effective July 1, 2024)

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.