

Effective: May 1, 2024

Guideline Type	<input type="checkbox"/> Prior Authorization <input type="checkbox"/> Non-Formulary <input checked="" type="checkbox"/> Step-Therapy <input type="checkbox"/> Administrative
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Applies to:

Public Plans Products

- 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

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)
Acromegaly	Lanreotide (ciplra) Signifor LAR	Sandostatin LAR Somatuline Depot
Antiemetics	Akynzeo Aponvie Cinvanti Sustol	fosaprepitant granisetron ondansetron palonosetron Aloxi Emend
Autoimmune	Avsola Renflexis	Inflectra Remicade Infliximab

Bendamustine HCl Injection	Treanda Vivimusta	bendamustine Bendeka Belrapzo
Bevacizumab – oncology	Avastin Alymsys Vegzelma	Mvasi Zirabev
Bone Resorption Inhibitors	Evenity Prolia Xgeva	ibandronate pamidronate zoledronic acid
Botulinum Toxins	Daxxify Dysport Myobloc	Botox Xeomin
Gaucher’s Disease	Elelyso	Cerezyme Vpriv
Iron Preparation, Parenteral	Feraheme Injectafer Monoferric	Ferrlecit Infed Venofer
Leucovorin / LEVOleucovorin Injection	Fusilev Khazory LEVOleucovorin	leucovorin injection
Neutropenia Colony Stimulating Agents – long acting	Fylmetra Nyvepria Rolvedon Stimufend Udenyca Ziextenzo	Fulphila Neulasta
Neutropenia Colony Stimulating Agents – short acting	Granix Leukine Neupogen Nivestym Releuko	Zarxio
Rare Disease	Soliris	Ultomiris
Retinal Disorders	Beovu Byooviz Cimerli Eylea Eylea HD Lucentis Susvimo Vabysmo Visudyne	Avastin
Rituximab	Rituxan Rituxan Hycela Riabni	Ruxience Truxima
Trastuzumab	Herceptin Herceptin Hylecta Herzuma Ogivri Ontruzant	Kanjinti Trazimera
Triamcinolone Acetonide Injection	Zilretta	triamcinolone acetonide injection
Viscosupplements	Durolane Gel-One Gelsyn-3 Genvisc 850 Hyalgan Hymovis Monovisc	Euflexxa

	Orthovisc Supartz FX Synojoynt Synvisc Synvisc One Triluron Trivisc Visco-3	
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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

Limitations

- Authorizations for a non-preferred product due to a drug shortage of a preferred product(s) will be limited to three (3) months.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J1932	Injection, lanreotide, (ciplra), 1 mg
J2502	Injection, pasireotide long acting, 1 mg
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
C9145	Injection, aprepitant, (aponvie), 1 mg
J0185	Injection, aprepitant, 1 mg
J1627	Injection, granisetron, extended-release, 0.1 mg
Q5121	Injection, infliximab-azzq, biosimilar (AVSOLA), 10 mg
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
J9033	Injection, bendamustine HCL (treanda), 1 mg
J9056	Injection, bendamustine hydrochloride. (vivimusta), 1 mg
J9035	Injection, bevacizumab, 10 mg
Q5126	Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg
Q5129	Injection, bevacizumab-adcd (Vegzelma), biosimilar, 10 mg
J3111	Injection, romosozumab-aqqg, 1 mg
J0897	Injection, denosumab, 1 mg
J0589	Injection, daxibotulinumtoxin A-lanm, 1 unit
J0586	Injection, abobotulinumtoxin A, 5 units
J0587	Injection, rimabotulinumtoxin B, 100 units
J3060	Injection, taliglucerase alfa, 10 units
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)
J1439	Injection, ferric carboxymaltose, 1 mg
J1437	Injection, ferric derisomaltose, 10 mg

HCPCS Codes	Description
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (khapzory), 0.5 mg
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5 mg
Q5122	Injection, pegfilgrastim-ppgf, biosimilar, (nyvepria), 0.5 mg
J1449	Injection, eflapegrastim-xnst, 0.1 mg
Q5127	Injection, pegfilgrastim-fpgk (Stimufend), biosimilar, 0.5 mg
Q5111	Injection, Pegfilgrastim-cbqv, biosimilar, (udenycya), 0.5 mg
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg
J1447	Injection, tbo-filgrastim, 1 microgram
J2820	Injection, sargramostim (GM-CSF), 50 mcg
J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 microgram
Q5110	Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram
Q5125	Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg
J1300	Injection, eculizumab, 10 mg
J0179	Injection, brolocizumab-dbll, 1 mg
Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1mg
Q5128	Injection, ranibizumab-eqrn (Cimerli), biosimilar, 0.1 mg
J0178	Injection, aflibercept, 1 mg
J0177	Injection, aflibercept HD, 1 mg
J2778	Injection, ranibizumab, 0.1 mg
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2777	Injection, faricimab-svoa, 0.1 mg
J3396	Injection, verteporfin, 0.1 mg
J9312	Injection, rituximab, (Rituxan)10 mg
J9311	Injection, rituximab 10 mg and hyaluronidase
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk
Q5113	Injection, trastuzumab-pkrb, 10 mg
Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5112	Injection, Trastuzumab-dttb, Biosimilar (Ontruzant), 10 mg
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 1 mg
J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
J7328	Hyaluronan or derivative, Gel-Syn, for intra-articular injection, 0.1 mg
J7320	Hyaluronan or derivative, Genvisc 850, for intra-articular injection, 1 mg
J7321	Hyaluronan or derivative, Hyalgan or Supartz, for intra-articular injection, per dose
J7322	Hyaluronan or derivative, Hymovis, for intra-articular injection, 1 mg
J7327	Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
J7324	Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose
J7331	Hyaluronan or derivative, SYNOJOYNT, for intra-articular injection, 1 mg
J7325	Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Trilon, for intra-articular injection, 1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7333	Hyaluronan or derivative, Visco-3, for intra-articular injection, per dose

Approval And Revision History

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

Subsequent endorsement date(s) and changes made:

- February 15, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)
- December 2022 added Vegzelma as non-preferred Bevacizumab oncology product effective February 1, 2023
- March 2023 added Stimufend and Rolvedon 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: Acromegaly, Antiemetics, Bone Resorption Inhibitors, and Botulinum Toxins. Updated the Gaucher Disease strategy to make Cerezyme a preferred product and Elelyso a non-preferred product. Updated the Leucovorin/LEVOleucovorin strategy by adding LEVOleucovorin as a non-preferred product. Updated the Trastuzumab strategy by moving Ogivri to a non-preferred product. Administrative update to rebrand Tufts Health Unify to Tufts Health One Care (effective January 1, 2024).
- December 12, 2024: Added Eylea HD and Daxxify to the Medical Necessity Guideline (effective January 1, 2024).
- February 13, 2024: Added the Limitation Authorizations for a non-preferred product due to a drug shortage of a preferred product(s) will be limited to three (3) months (effective May 1, 2024).
- May 2024: Administrative update to add HCPC codes for non-preferred products (effective May 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.