Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Medicare Part B Step Therapy

Effective: January 1, 2027

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

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

☒ 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	Signifor LAR Somatuline Depot	lanreotide lanreotide (cipla) Sandostatin LAR
Antiemetics	Akynzeo Aponvie Cinvanti Emend Focinvez Posfrea Sustol	fosaprepitant granisetron ondansetron palonosetron
Autoimmune	Infliximab Remicade Renflexis Zymfentra	Avsola Inflectra
	Imuldosa Otulfi Pyzchiva Selarsdi	Steqeyma Yesintek

	Stelara Weslana	
Bendamustine HCl Injection	Bendeka Treanda -brand Vivimusta	bendamustine – generic Belrapzo
Bevacizumab – oncology	Avastin Alymsys Vegzelma Jobevne	Mvasi Zirabev
Bone Resorption Inhibitors (Step does not apply to Xgeva in the setting of Prostate or Breast Cancer)	Evenity Prolia Xgeva Enoby Xtrenbo Bosaya Conexxence Jubbonti Ospomyv Osvyrti Aukelso Bomyntra Jubereq Wyost	Step 1: ibandronate pamidronate zoledronic acid Step 2: Stoboclo Osenvelt Bildyos Bilprevda Enoby Xtrenbo
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	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 Nypozi Releuko Filkri	Zarxio
Pemetrexed	Alimta - brand Pemfexy Pemrydi	Pemetrexed (all manufacturers) – generic
Rare Disease	Soliris Bkemv Epysqli	Ultomiris
Retinal Disorders	Beovu Byooviz Cimerli Eydenzelt Eylea	Avastin Aflibercept* Ranibizumab*

	Eylea HD Lucentis Opuviz Pavblu Susvimo Visudyne Vabysmo	
Rituximab	Rituxan Rituxan Hycela Riabni	Ruxience Truxima
Trastuzumab	Herceptin Herceptin Hylecta Hercessi Herzuma Ogivri Ontruzant	Kanjinti Trazimera
Triamcinolone Acetonide Injection	Zilretta	triamcinolone acetonide injection
Viscosupplements	Durolane Gel-One Gelsyn-3 Genvisc 850 Hyalgan Hymovis Monovisc Orthovisc Supartz FX Synojoynt Synvisc Synvisc One Triluron Trivisc Visco-3	Euflexxa

*Biosimilar or reference product

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.

Acromegaly

The plan may authorize coverage of a non-preferred Acromegaly product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Acromegaly product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Acromegaly product within the past 365 days

Antiemetics

The plan may authorize coverage of a non-preferred Antiemetic product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Antiemetic product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Antiemetic product within the past 365 days

Autoimmune

The plan may authorize coverage of a non-preferred Autoimmune product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of a trial of at least 14 weeks of at least one preferred Autoimmune product resulting in a substandard response to therapy

b. Continuation of prior therapy with the requested non-preferred Autoimmune product within the past 365 days

Bendamustine HCl Injection

The plan may authorize coverage of a non-preferred Bendamustine HCl Injection product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Bendamustine HCl Injection product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Bendamustine HCl Injection product within the past 365 days

Bevacizumab – Oncology

The plan may authorize coverage of a non-preferred Bevacizumab – Oncology product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Bevacizumab – Oncology product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Bevacizumab – Oncology product within the past 365 days

Bone Resorption Inhibitors

The plan may authorize coverage of a non-preferred Bone Resorption Inhibitor product (with the exception of Evenity) when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one Bone Resorption Inhibitor product on step-2 resulting in a substandard response to therapy (For Evenity:
    b. Continuation of prior therapy with the requested non-preferred Bone Resorption Inhibitor product within the past 365 days

The plan may authorize coverage of a preferred Bone Resorption Inhibitor product on step-2 and Evenity when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    c. History of use of at least one Bone Resorption Inhibitor product on step-1 resulting in a substandard response to therapy
    d. Continuation of prior therapy with the requested non-preferred Bone Resorption Inhibitor product within the past 365 days

Botulinum Toxins

The plan may authorize coverage of a non-preferred Botulinum Toxin product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Botulinum Toxin product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Botulinum Toxin product within the past 365 days

Gaucher's Disease

The plan may authorize coverage of a non-preferred Gaucher's Disease product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Gaucher's Disease product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Gaucher's Disease product within the past 365 days

Iron Preparation, Parental

The plan may authorize coverage of a non-preferred Iron Preparation, Parental product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of a trial of at least three (3) weeks of at least one preferred Iron Preparation, Parental product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Iron Preparation, Parental product within the past 365 days

Leucovorin / LEVOleucovorin Injection

The plan may authorize coverage of a non-preferred Leucovorin / LEVOleucovorin Injection product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Leucovorin / LEVOleucovorin Injection product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Leucovorin / LEVOleucovorin Injection product within the past 365 days

Neutropenia Colony Stimulating Agents – Long-acting

The plan may authorize coverage of a non-preferred Neutropenia Colony Stimulating Agents – Long-acting product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Neutropenia Colony Stimulating Agents – Long-acting product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Neutropenia Colony Stimulating Agents – Long-acting product within the past 365 days

Neutropenia Colony Stimulating Agents – Short-acting

The plan may authorize coverage of a non-preferred Neutropenia Colony Stimulating Agents – Short-acting product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Neutropenia Colony Stimulating Agents – Short-acting product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Neutropenia Colony Stimulating Agents – Short-acting product within the past 365 days

Pemetrexed

The plan may authorize coverage of a non-preferred Pemetrexed product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    c. History of use of at least one preferred Pemetrexed product resulting in a substandard response to therapy
    d. Continuation of prior therapy with the requested non-preferred Pemetrexed product within the past 365 days

Rare Disease

The plan may authorize coverage of a non-preferred Rare Disease product when **ALL** of the following criteria are met:

1. Documentation of one (1) of the following:
    a. History of use of at least one preferred Rare Disease product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Rare Disease product within the past 365 days

Retinal Disorders

The plan may authorize coverage of Beovu, Byooviz, Cimerli, Eylea, Lucentis, Opuviz, Pavblu, Susvimo, or Visudyne when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of a trial of at least 3 consecutive doses of Avastin in either eye given monthly resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Retinal Disorders product within the past 365 days

The plan may authorize coverage of Eylea HD or Vabysmo when **ALL** of the following criteria are met:

2. Documentation of **one (1)** of the following:
    a. Both of the following:
        i. History of a trial of at least 3 consecutive doses of Avastin in either eye given monthly resulting in a substandard response to therapy
        ii. History of a trial of aflibercept (biosimilar or reference product) or ranibizumab (biosimilar or reference product) resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Retinal Disorders product within the past 365 days

Rituximab

The plan may authorize coverage of Rituxan or Riabni when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Rituximab product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Rituximab product within the past 365 days

The plan may authorize coverage of Rituxan Hycela when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Rituximab product resulting in a substandard response to therapy
    b. Inability to obtain or maintain intravenous access
    c. Continuation of prior therapy with the requested non-preferred Rituximab product within the past

Trastuzumab

The plan may authorize coverage of Hercessi, Herceptin, Herzuma, Ogivri, or Ontruzant when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Trastuzumab product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Trastuzumab product within the past 365 days

The plan may authorize coverage of Herceptin Hylecta when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Trastuzumab product resulting in a substandard response to therapy
    b. Inability to obtain or maintain intravenous access
    c. Continuation of prior therapy with the requested non-preferred Trastuzumab product within the past 365 days

Triamcinolone Acetonide Injection

The plan may authorize coverage of a non-preferred Triamcinolone Acetonide Injection product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of use of at least one preferred Triamcinolone Acetonide Injection product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Triamcinolone Acetonide Injection product within the past 365 days

Viscosupplements

The plan may authorize coverage of a non-preferred Viscosupplement product when **ALL** of the following criteria are met:

1. Documentation of **one (1)** of the following:
    a. History of one course of at least one preferred Viscosupplement product resulting in a substandard response to therapy
    b. Continuation of prior therapy with the requested non-preferred Viscosupplement product within the past 365 days

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
C9145	Injection, aprepitant, (aponvie), 1 mg
J0177	Injection, aflibercept HD, 1 mg
J0178	Injection, aflibercept, 1 mg
J0179	Injection, brolucizumab-dbll, 1 mg
J0185	Injection, aprepitant, 1 mg
J0586	Injection, abobotulinumtoxin A, 5 units
J0587	Injection, rimabotulinumtoxin B,100 units

HCPCS Codes	Description
J0589	Injection, daxibotulinumtoxin A-lanm, 1 unit
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (khapzory), 0.5 mg
J0644	Injection, leucovorin calcium (avyxa), 1 mg
J0643	Injection, leucovorin calcium, not otherwise specified, 1 mg
J0897	Injection, denosumab, 1 mg
J1299	Injection, eculizumab, 2 mg
J1434	Injection, fosaprepitant (focinvez), 1 mg
J1437	Injection, ferric derisomaltose, 10 mg
J1439	Injection, ferric carboxymaltose, 1 mg
J1442	Injection, filgrastim (G-CSF), excludes biosimilars, 1 microgram
J1447	Injection, tbo-filgrastim, 1 microgram
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
J1627	Injection, granisetron, extended-release, 0.1 mg
J1745	Injection, infliximab, excludes biosimilar, 10 mg
J1748	Injection, infliximab-dyyb, 10 mg
J1930	Injection, lanreotide, 1 mg
J2468	Injection, palonosetron hydrochloride (posfrea), 25 micrograms
J2502	Injection, pasireotide long acting, 1 mg
J2777	Injection, faricimab-svoa, 0.1 mg
J2778	Injection, ranibizumab, 0.1 mg
J2779	Injection, ranibizumab, via intravitreal implant (susvimo), 0.1 mg
J2820	Injection, sargramostim (GM-CSF), 50 mcg
J3060	Injection, taliglucerase alfa, 10 units
J3111	Injection, romosozumab-aqqg, 1 mg
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg
J3396	Injection, verteporfin, 0.1 mg
J7318	Hyaluronan or derivative, Durolane, for intra-articular injection, 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
J7324	Hyaluronan or derivative, Orthovisc, for intra-articular injection, per dose
J7325	Hyaluronan or derivative, Synvisc or Synvisc-One, for intra-articular injection, 1 mg
J7326	Hyaluronan or derivative, Gel-One, for intra-articular injection, per dose
J7327	Hyaluronan or derivative, Monovisc, for intra-articular injection, per dose
J7328	Hyaluronan or derivative, Gel-Syn, for intra-articular injection, 0.1 mg
J7329	Hyaluronan or derivative, Trivisc, for intra-articular injection, 1 mg
J7331	Hyaluronan or derivative, SYNOJOYNT, for intra-articular injection, 1 mg
J7332	Hyaluronan or derivative, Triluron, for intra-articular injection, 1 mg
J8502	Injection, aprepitant (aponvie), 1 mg
J9033	Injection, bendamustine HCL (treanda), 1 mg
J9034	Injection, bendamustine HCl (Bendeka), 1 mg
J9035	Injection, bevacizumab, 10 mg
J9056	Injection, bendamustine hydrochloride. (vivimusta), 1 mg
J9304	Injection, pemetrexed (pemfexy), 10 mg

HCPCS Codes	Description
J9066	Injection, bendamustine hydrochloride (avyxa), 1 mg
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, (Rituxan)10 mg
J9324	Injection, pemetrexed (pemrydi rtu), 10 mg
J9355	Injection, trastuzumab, excludes biosimilar, 10 mg
J9356	Injection, trastuzumab, 10 mg and Hyaluronidase-oysk
J9361	Injection efbemalenograstim alfa-vuxw 0.5 mg
Q0138	Injection, ferumoxytol, for treatment of iron deficiency anemia, 1 mg (non-ESRD use)
Q5104	Injection, infliximab-abda, biosimilar, (Renflexis), 10 mg
Q5110	Injection, filgrastim-aafi, biosimilar, (Nivestym), 1 microgram
Q5111	Injection, pegfilgrastim-cbqv, biosimilar, (udenyca), 0.5 mg
Q5112	Injection, Trastuzumab-dttb, Biosimilar (Ontruzant), 10 mg
Q5113	Injection, trastuzumab-pkrb, 10 mg
Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5120	Injection, pegfilgrastim-bmez, biosimilar, (ziextenzo), 0.5 mg
Q5122	Injection, pegfilgrastim-apgf, biosimilar, (nyvepria), 0.5 mg
Q5123	Injection, rituximab-arrx, biosimilar, (riabni), 10 mg
Q5124	Injection, ranibizumab-nuna, biosimilar, (byooviz), 0.1mg
Q5125	Injection, filgrastim-ayow, biosimilar, (Releuko), 1 mcg
Q5126	Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg
Q5127	Injection, pegfilgrastim-fpgk (Stimufend), biosimilar, 0.5 mg
Q5128	Injection, ranibizumab-eqrn (Cimerli), biosimilar, 0.1 mg
Q5129	Injection, bevacizumab-adcd (Vegzelma), biosimilar, 10 mg
Q5130	Injection, pegfilgrastim-pbbk (Fylnetra), biosimilar, 0.5 mg
Q5146	Injection, trastuzumab-strf (Hercessi), biosimilar, 10 mg
Q5147	INJ, AFLIBERCEPT-AYYH, 1 MG
Q5147	Injection, aflibercept-ayyh (pavblu), biosimilar, 1 mg
Q5148	Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram
Q5153	Injection, aflibercept-yszy (opuviz), biosimilar, 1 mg
Q5160	Injection, bevacizumab-nwgd (jobevne), biosimilar, 10 mg
Q5152	Injection, eculizumab-aeeb (bkemv), biosimilar, 2 mg
Q5151	Injection, eculizumab-aagh (epysqli), biosimilar, 2 mg
Q5167	Injection, denosumab-qbde [enoby/xtrenbo], biosimilar, 1 mg
Q5172	Injection, filgrastim-laha (filkri), biosimilar, 1 microgram

References

1. Flaxel CJ, Adelman RA, Bailey ST, Representative RS, Fawzi A, Representative MS, Lim JI, Vemulakonda GA, Ying G-s, Age-Related Macular Degeneration Preferred Practice Pattern®, Ophthalmology (2019), doi: https://doi.org/10.1016/j.ophtha.2019.09.024.
2. INFeD (iron dextran injection) [prescribing information]. North Chicago, IL: AbbVie Inc.; August 2024.
3. Remicade (infliximab) [prescribing information]. Horsham, PA: Janssen Biotech, Inc.; February 2025.

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)
- June 11, 2024: Added Ryzneuta and Zymfentra 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).
- August: 13, 2024: Added Focinvez to the Medical Necessity Guideline (effective October 1, 2024).
- September 10, 2024: Updated coverage criteria to be drug class specific. For Acromegaly Products, moved lanreotide (cipla) to preferred status and moved brand Somatuline Depot to non-preferred status, and added lanreotide (generic Somatuline Depot) as a preferred product. For Antiemetics, removed Aloxi as a preferred product due to product discontinuation. For Retinal Disorders, added a second step for Eylea HD and Vabysmo. Added Pemetrexed drug class to Medical Necessity Guideline (effective January 1, 2025).
- September 2024: Joint Medical Policy and Heath Care Services UM Committee review (effective October 1, 2024 and January 1, 2025, respectively).
- December 10, 2024: Added Hercessi, Nypozi, and Pavblu to the Medical Necessity Guideline. Clarified language for Eylea HD and Vabysmo to indicate that a biosimilar or reference product of aflibercept or ranibizumab qualifies (eff 1/1/25).
- December 2024: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/25).
- February 11, 2025: Removed the Limitation “Authorizations for a non-preferred product due to a drug shortage of all preferred products will be limited to three (3) months.” Administrative update to remove Harvard Pilgrim Health Care Stride Medicare Advantage from the Medical Necessity Guideline template (eff 4/1/25)
- March 11, 2025: Administrative Update: Removed J Codes: J1300 and C9173. Added J Codes: J1299, Q5147, and Q5148. (eff 4/1/25)
- March 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 4/1/25).
- June 10, 2025: Added Opuviz to the Medical Necessity Guideline. Administrative update to add the HCPCS code for Pavblu. Removed brand Fusilev as a non-preferred product because the product has been discontinued (eff 7/1/25). Add Posfrea to the Medical Necessity Guideline. Move brand Emend and brand Bendeka as a non-preferred product (eff 10/1/25).
- June 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 7/1/25 and 10/1/25).
- September 9, 2025: Updated Autoimmune strategy to move Avsola to a preferred product and Remicade and Infliximab to non-preferred products (eff 1/1/26).
- September 2025: Joint Medical Policy and Health Care Services: UM Committee review (eff 1/1/26).
- April 2026: Administrative update to add HCPCs code, J8502 (Aponvie), to guideline, effective 4/1/26.
- March 10, 2026: Added Eydenzelt to the guideline (eff 4/1/26)
- September 2026: Administrative Update: Added J Codes (J9066) Bendamustine, (J0643) leucovorin calcium, NOS, and (J0644) leucovorin calcium (avyxa); Added Jobevne, Bkemv, Epysqli, Enoby, Xtrenbo, and FIlkri to non-preferred status; Added ustekinumab category with steqeyma and yesintek preferred (eff 1/1/27)
- September 2026: Joint Medical Policy and Health Care Services UM Committee review (Effective 1/1/27): Added a second step to obtain non-preferred denosumab products. Stoboclo, Osenvelt, Bildyos, Biprevda, Enoby, and Xtrenbo will be step-2 (or preferred products within the denosumab product line)

Background, Product and Disclaimer Information

Point32Health prior authorization criteria to be applied to Medicare Advantage plan members is based on guidance from Medicare laws, National Coverage Determinations (NCDs) or Local Coverage Determinations (LCDs). When no guidance is provided, Point32Health uses clinical practice guidance published by relevant medical societies, relevant medical literature, Food and Drug Administration (FDA)-approved package labeling, and drug compendia to develop prior authorization criteria to apply to Medicare Advantage plan members. Medications that require prior authorization generally meet one or more of the following criteria: Drug product has the potential to be used for cosmetic purposes; drug product is not considered as first-line treatment by medically accepted practice guidelines, evidence to support the safety and efficacy of a drug product is poor, or drug product has the potential

to be used for indications outside of the indications approved by the FDA. Prior authorization and use of the coverage criteria within this Medical Necessity Guideline will ensure drug therapy is medically necessary, clinically appropriate, and aligns with evidence-based guidelines. We revise and update Medical Necessity Guidelines annually, or more frequently if new evidence becomes available that suggests revisions.

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.