Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Medical Benefit Step Therapy

Effective: January 1, 2025

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

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 Sustol	fosaprepitant granisetron ondansetron palonosetron
Bendamustine HCl Injection	Bendeka Treanda Vivimusta	bendamustine Belrapzo
Iron Preparation, Parenteral	Feraheme Injectafer Monoferric	Ferrlecit Infed Venofer
Leucovorin / LEVOleucovorin Injection	Fusilev Khapzory LEVOleucovorin	leucovorin injection

Pemetrexed	Alimta Pemfexy Pemrydi	Pemetrexed (all manufacturers)
Retinal Disorders	Beovu Byooviz Cimerli Eylea Lucentis Pavblu Susvimo Visudyne	Avastin
	Eylea HD Vabysmo	Aflibercept* Avastin Ranibizumab*
Triamcinolone Acetonide Injection	Zilretta	Triamcinolone acetonide injection

*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 a history of use of at least one preferred Acromegaly product resulting in a substandard response to therapy

Antiemetics

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

1. Documentation of a history of use of at least one preferred Antiemetic product resulting in a substandard response to therapy

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 a history of use of at least one preferred Bendamustine HCl Injection product resulting in a substandard response to therapy

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 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

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 a history of use of at least one preferred Leucovorin / LEVOleucovorin Injection product resulting in a substandard response to therapy

Pemetrexed

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

1. Documentation of a history of use of at least one preferred Pemetrexed product resulting in a substandard response to therapy

Retinal Disorders

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

1. Documentation of 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

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

2. Documentation of **both** 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. History of a trial of aflibercept (biosimilar or reference product) or ranibizumab (biosimilar or reference product) resulting in a substandard response to therapy

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 a history of use of at least one preferred Triamcinolone Acetonide Injection product resulting in a substandard response to therapy

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J2502	Injection, pasireotide long acting, 1 mg
J1930	Injection, lanreotide, 1 mg
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
C9145	Injection, aprepitant, (aponvie), 1 mg
J0185	Injection, aprepitant, 1 mg
J1434	Injection, fosaprepitant (focinvez), 1 mg
J1627	Injection, granisetron, extended-release, 0.1 mg
J9034	Injection, bendamustine HCl (Bendeka), 1 mg
J9056	Injection, bendamustine hydrochloride. (vivimusta), 1 mg
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
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0642	Injection, levoleucovorin (khapzory), 0.5 mg
J9304	Injection, pemetrexed (pemfexy), 10 mg
J9324	Injection, pemetrexed (pemrydi rtu), 10 mg
J0179	Injection, brolucizumab-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

HCPCS Codes	Description
J3396	Injection, verteporfin, 0.1 mg
J3304	Injection, triamcinolone acetonide, preservative-free, extended-release, microsphere formulation, 1 mg
Q5147	INJ, AFLIBERCEPT-AYYH, 1 MG

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.; October 2021.

Approval And Revision History

September 10, 2024: Reviewed by Pharmacy and Therapeutics Committee (P&T) (eff 1/1/25)

December 10, 2024: Added 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).

Subsequent endorsement date(s) and changes made:

- March 11, 2025: Administrative updates: Added J Code: Q5147. (Eff 4/1/25)

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.