Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines:
Medical Benefit Drugs
Medical Benefit Step Therapy

Effective: October 1, 2026

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

☐ 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.

Clinical Guideline Coverage Criteria

Drug Class	Non-preferred Product(s)	Preferred Product(s)
IV Antiemetics	Akynzeo (J1454) Cinvanti (J0185) Emend – Brand (J1453) Focinvez (J1434) Sustol (J1627) Posfrea (J2468) Aponvie (J8502)	**Fosaprepitant - Generic (J1453)** **Fosaprepitant (J1456)** **Granisetron (J1626)** – No PA Required **Ondansetron (J2405)** – No PA Required **Palonosetron (J2469)** – No PA Required
Bendamustine HCl Injection	Bendeka (J9034) Treanda – Brand (J9033) Vivimusta (J9056)	**Bendamustine – Generic (J9033)** **Belrapzo (J9036)**
Bevacizumab	Avastin (J9035) Alymsys (Q5126) Avizivi (J9999) Jobevne (Q5160) Vegzelma (Q5129)	**Mvasi (Q5107)** – No PA Required **Zirabev (Q5118)** – No PA Required
Denosumab – Xgeva* *Step does not apply in the setting of Prostate or Breast Cancer	Aukelso (J3590) Bilprevda (J3590) Bomyntra (Q5158) Osenvelt (Q5157) Wyost (Q5136) Xgeva (J0897)	**Zoledronic Acid (J3489)** – No PA Required

(Drug specific policy also exists and defines medical necessity)	Xtrenbo (J3590) Jubereq (Q5166) Oziltus (Q5165) Xbryk (Q5159)	
Leucovorin / LEVOleucovorin Injection	LEVOleucovorin (J0641) Khapzory (J0642) Vykoura (J0644)	**Leucovorin injection (J0643)**** – No PA Required **If at any time leucovorin (J0643) is unavailable from any manufacturer per the FDA Drug shortage website (https://www.accessdata.fda.gov/scripts/drugshortages/default.cfm), Levoleucovorin (J0641) will be preferred over Khapzory (J0642). In this instance, Levoleucovorin (J0641) will still require Prior Authorization.
Long-Acting GCSFs	Rolvedon (J1449) Ryzneuta (J9361) Udenyca (Q5111) Ziextenzo (Q5120) Nyvepria (Q5122) Stimufend (Q5127) Fylnetra (Q5130) Armlupeg (Q5169)	**Neulasta (J2506)** – No PA Required **Fulphila (Q5108)** – No PA Required
Non-Muscle Invasive Bladder Cancer	Anktiva (J9028) Inlexzo (J9183)	**Adstiladrin (J9029)** **Keytruda (J9271)** **Keytruda Qlex (J9277)**
Pemetrexed	Alimta – Brand (J9305) Pemfexy (J9304) Pemrydi (J9324)	**Pemetrexed – Generic (J9305)** **Pemetrexed, Hospira (J9294)** **Pemetrexed, Accord (J9296)** **Pemetrexed, Avyxa (J9292)** **Pemetrexed, Sandoz (J9297)** **Pemetrexed, Teva (J9314)** **Pemetrexed, Bluepoint (J9322)** **Pemetrexed, Hospira (J9323)** **Pemetrexed, Apotex (J9999)**
Rituximab	Rituxan (J9312) Rituxan Hycela (J9311) Riabni (Q5123)	**Truxima (Q5115)** **Ruxience (Q5119)**
Short-Acting GCSFs	Neupogen (J1442) Granix (J1447) Nivestym (Q5110) Nypozi (Q5148) Releuko (Q5125) Filkri (Q5172)	**Zarxio (Q5101)** – No PA Required
Trastuzumab	Herceptin (J9355) Herceptin Hylecta (J9356) Hercessi (Q5146) Ontruzant (Q5112) Herzuma (Q5113) Ogivri (Q5114)	**Trazimera (Q5116)** – No PA Required **Kanjinti (Q5117)** – No PA Required
• Member must have documentation of a history of use of at least one preferred product resulting in substandard response to therapy **OR** documentation of continuation of prior therapy with the requested non-preferred agent within the past 365 days is provided • Step Therapy applies to all overlapping compendia supported indications/regimens.		

Universal Approval Criteria:

Unless otherwise noted, the review criteria used to determine medical necessity for anticancer treatments and supportive agents include, but is not limited to:

- National Comprehensive Cancer Network® (NCCN) - use consistent with NCCN recommendations carrying a Category 1 or 2A level of evidence; **OR**
- United States Food and Drug Administration (FDA) labeling - new drugs or regimens (combinations of drugs) consistent with all components of the product labeling; **OR**
- Indications not included in the official FDA labeling or recommended by NCCN (Category 1 or 2A level of evidence) may be

considered if determined to be medically necessary per one or more of the following compendia:

- Clinical Pharmacology (Strong For); **OR**
- Wolters Kluwer Lexi-Drugs® (Level A); **OR**

- Other uses of drugs and biologics may be considered medically necessary if supported as safe and effective according to peer-reviewed articles from one of the following journals:
  - American Journal of Medicine; Annals of Internal Medicine; Annals of Oncology; Annals of Surgical Oncology; Biology of Blood and Marrow Transplantation; Blood; Bone Marrow Transplantation; British Journal of Cancer; British Journal of Hematology; British Medical Journal; Cancer; Clinical Cancer Research; Drugs; European Journal of Cancer (formerly the European Journal of Cancer and Clinical Oncology); Gynecologic Oncology; International Journal of Radiation, Oncology, Biology, and Physics; The Journal of the American Medical Association, Journal of Clinical Oncology; Journal of the National Cancer Institute; Journal of the National Comprehensive Cancer Network (NCCN); Journal of Urology; Lancet; Lancet Oncology; Leukemia; The New England Journal of Medicine; Radiation Oncology;
  - **Meeting abstracts and case reports are excluded from consideration;**
- Non-standard protocols may be approved based on unique clinical circumstances;
- Dose and frequency should be consistent with United States Food and Drug Administration (FDA) labeling, National Comprehensive Cancer Network® (NCCN), or indication specific peer-reviewed literature;
- In the instance that a request is made for drug(s) that was (were) previously tried (including in the same pharmacologic class or with the same mechanism of action) and such drug(s) was (were) discontinued due to a lack of efficacy the request may be subject to an off-label review for medical necessity unless supported by the NCCN or high quality literature (prospective phase 2 or 3 studies published as full manuscripts in a CMS-supported journal).

Limitations

- None

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J0185	Injection, aprepitant, 1 mg
J0641	Injection, levoleucovorin, not otherwise specified, 0.5 mg
J0644	Injection, leucovorin calcium (avyxa), 1 mg
J0642	Injection, levoleucovorin (khapzory), 0.5 mg
J0897	Injection, denosumab, 1 mg
J1434	Injection, fosaprepitant (focinvez), 1 mg
J1442	Injection, filgrastim (g-csf), excludes biosimilars, 1 microgram
J1447	Injection, tbo-filgrastim, 1 microgram
J1449	Injection, eflapegrastim-xnst, 0.1 mg
J1453	Injection, fosaprepitant, 1 mg
J1454	Injection, fosnetupitant 235 mg and palonosetron 0.25 mg
J1456	Injection, fosaprepitant (teva), not therapeutically equivalent to j1453, 1 mg
J1627	Injection, granisetron, extended-release, 0.1 mg
J2468	Injection, palonosetron hydrochloride (posfrea), 25 micrograms
J2506	Injection, pegfilgrastim, excludes biosimilar, 0.5 mg
J3590	Unclassified biologics = Aukelso (Permanent HCPCS Pending)
J8502	Injection, aprepitant (Aponvie), 1 mg
J9028	Injection, nogapendekin alfa inbakicept-pmln, for intravesical use, 1 microgram
J9033	Injection, bendamustine hydrochloride, 1 mg
J9034	Injection, bendamustine hcl (bendeka), 1 mg

HCPCS Codes	Description
J9035	Injection, bevacizumab, 10 mg
J9036	Injection, bendamustine hydrochloride, (belrapzo/bendamustine), 1 mg
J9056	Injection, bendamustine hydrochloride (vivimusta), 1 mg
J9036	Injection, bendamustine hydrochloride (apotex), 1 mg
J9036	Injection, bendamustine hydrochloride (baxter), 1 mg
J9183	Gemcitabine intravesical system, 225 mg
J9264	Injection, paclitaxel protein-bound particles, 1 mg
J9292	Injection, pemetrexed (avyxa), not therapeutically equivalent to J9305, 10 mg
J9294	Injection, pemetrexed (hospira) not therapeutically equivalent to J9305, 10 mg
J9296	Injection, pemetrexed (accord) not therapeutically equivalent to J9305, 10 mg
J9297	Injection, pemetrexed (sandoz), not therapeutically equivalent to J9305, 10 mg
J9304	Injection, pemetrexed (pemfexy), 10 mg
J9305	Injection, pemetrexed, not otherwise specified, 10 mg
J9311	Injection, rituximab 10 mg and hyaluronidase
J9312	Injection, rituximab, 10 mg
J9314	Injection, pemetrexed (teva) not therapeutically equivalent
J9322	Injection, pemetrexed (bluepoint) not therapeutically equivalent to J9305, 10 mg
J9323	Injection, pemetrexed ditromethamine, 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
J9999	Not otherwise classified
Q5108	Injection, pegfilgrastim-jmdb, biosimilar, (Fulphila), 0.5 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, biosimilar, (Herzuma), 10 mg
Q5114	Injection, Trastuzumab-dkst, biosimilar, (Ogivri), 10 mg
Q5115	Injection, rituximab-abbs, biosimilar, (Truxima), 10 mg
Q5119	Injection, rituximab-pvvr, biosimilar, (Ruxience), 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
Q5125	Injection, filgrastim-ayow, biosimilar, (releuko), 1 microgram
Q5126	Injection, bevacizumab-maly, biosimilar, (Alymsys), 10 mg
Q5127	Injection, pegfilgrastim-apgf, biosimilar, (Stimufend), 0.5 mg
Q5129	Injection, bevacizumab-adcd (Vegzelma), biosimilar, 10 mg
Q5130	Injection, pegfilgrastim-apgf, biosimilar, (Fylnetra), 0.5 mg
Q5136	Injection, denosumab-bbdz (jubbonti/wyost), biosimilar, 1 mg
Q5146	Injection, trastuzumab-strf (Hercessi), biosimilar, 10 mg
Q5148	Injection, filgrastim-txid (nypozi), biosimilar, 1 microgram
Q5157	Injection, denosumab-bmwo (stoboclo/osenvelt), biosimilar, 1 mg
Q5158	Injection, denosumab-bnht (bomyntra/conexxence), biosimilar, 1 mg
Q5159	Injection, denosumab-dssb (ospomyv/xbryk), biosimilar, 1 mg

HCPCS Codes	Description
Q5160	Injection, bevacizumab-nwgd (jobevne), biosimilar, 10 mg
Q5165	Injection, denosumab-mobz (Oziltus), biosimilar, 1 mg
Q5166	Injection, denosumab-desu (Osvyrti/Jubereq), biosimilar, 1 mg
Q5169	Injection, pegfilgrastim-unne (Armlupeg), biosimilar, 0.5 mg
Q5172	Injection, filgrastim-laha (filkri), biosimilar, 1 microgram

References

None

Approval And Revision History

June 10, 2025: Reviewed by Pharmacy and Therapeutics Committee (P&T) (eff 1/1/26).

June 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/26).

December 9, 2025: Removed Tufts Health Plan Senior Care Options from the Medical Necessity Guideline. Added Aukelso, Bilprevda, Bomyntra, Osenvelt, and Wyost to the Medical Necessity Guideline as non-preferred Bone Resorption Inhibitors. Updated HCPCS code for Jobevne (eff 1/1/26).

December 2025: Joint Medical Policy and Health Care Services UM Committee review (eff 1/1/26).

December 12, 2025: Added Xtrenbo as non-preferred under Bone Resorption Inhibitors

June 2026: Joint Medical Policy and Health Care Services UM Committee review (effective 10/1/26): Added new category for Non-Muscle Invasive Bladder Cancer making Anktiva and Inlexzo non-preferred

September 2026: Joint Medical Policy and Health Care Services UM Committee review (Effective 10/1/26): Added Xgeva biosimilars: Oziltus, Xbryk and Jubereq. Added Neulasta biosimilar: Armlupeg and Nupogen biosimilar: Filkri. Added Aponvie and Vykoura.

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.