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.

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)	**Fosaprepitant - Generic (J1453)** **Fosaprepitant (J1456)** **Granisetron (J1626)** – No PA Required **Ondansetron (J2405)** – No PA Required **Palonosetron (J2469)** – No PA Required
Bevacizumab	Avastin (J9035) Alymsys (Q5126) Vegzelma (Q5129)	**Mvasi (Q5107)** – No PA Required **Zirabev (Q5118)** – No PA Required
Bendamustine HCl Injection	Treanda – Brand (J9033) Bendeka (J9034) Vivimusta (J9056)	**Bendamustine – Generic (J9033)** **Bendamustine, Apotex (J9036)** **Bendamustine, Baxter (J9036)** **Belrapzo (J9036)**
Denosumab – Xgeva* *Step does not apply in the setting of Prostate or Breast Cancer (Drug specific policy also exists and defines medical necessity)	Xgeva (J0897)	**Zoledronic Acid (J3489)** – No PA Required

Leucovorin / LEVOleucovorin Injection	LEVOleucovorin (J0641) Khapzory (J0642)	**Leucovorin injection (J0640)**** – No PA Required **If at any time leucovorin (J0640) 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 (Drug specific policy also exists and defines medical necessity)	Rolvedon (J1449) Ryzneuta (J9361) Udenyca (Q5111) Ziextenzo (Q5120) Nyvepria (Q5122) Stimufend (Q5127) Flynetra (Q5130)	**Neulasta (J2506)** **Fulphila (Q5108)**
Paclitaxel Protein Bound*** ***Step does not apply in the setting of Pancreatic Cancer, Ampullary Adenocarcinoma, and Biliary Tract Cancers	Abraxane (J9264) Paclitaxel Protein-Bound (J9264)	**Paclitaxel (J9267)** – No PA Required **Docetaxel (J9171)** – No PA Required
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 (Drug specific policy also exists and defines medical necessity)	Neupogen (J1442) Granix (J1447) Nivestym (Q5110) Releuko (Q5125)	**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** member must have documentation of a contraindication, failure, or intolerance to any of the preferred agents prior to approval of a non-preferred product. • **Preferred product requirements apply to ALL requests, both new starts and reauthorizations.** • 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

- Authorizations are issued for 6 (six) months, unless the ordering physician requests a different timespan or the patients' unique circumstance or condition supports the medical necessity for a different authorization timeframe. Reauthorization requests are reviewed for efficacy, safety and tolerability.

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
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
J9033	Injection, bendamustine hydrochloride, 1 mg
J9034	Injection, bendamustine hcl (bendeka), 1 mg
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
J9264	Injection, paclitaxel protein-bound particles, 1 mg
J9292	Injection, pemetrexed (avyxa), not therapeutically equivalent to J9305, 10 mg

HCPCS Codes	Description
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, antineoplastic drugs = Pemetrexed, Apotex (Permanent HCPCS Pending)
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
Q5146	Injection, trastuzumab-strf (Hercessi), biosimilar, 10 mg

References

None

Approval And Revision History

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

- November 12, 2024: Administrative updates. Addition of Universal Criteria, duration of approval rules, and clarification that step therapy requirements apply to all requests for non-preferred agents. Added the following existing step therapy programs within OncoHealth policies to the Medical Benefit Step Therapy Medical Necessity Guideline: Bevacizumab, Denosumab - Xgeva, Long-acting GCFs, Paclitaxel Protein Bound, Rituximab, Short-acting GCSFs, Trastuzumab. Added pemetrexed (avyxa) HCPCS code J9292 as a preferred pemetrexed agent. Updated the following HCPCS codes: J9999 to Q5146, J9058 to J9036, J9259 to J9264, and J9059 to J9036. Updated the descriptions of the following HCPCS Codes: J2468 and J9033 (eff 1/1/25).

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.