Harvard Pilgrim Health Care | TUFTS Health Plan

Medical Necessity Guidelines
Medical Benefit Drugs
Abraxane® (paclitaxel protein bound)

Effective: January 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

☐ 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

Food and Drug Administration (FDA) - Approved Indications

Abraxane (paclitaxel protein-bound) is a microtubule inhibitor indicated for the treatment of:

- Metastatic breast cancer, after failure of combination chemotherapy for metastatic disease or relapse within 6 months of adjuvant chemotherapy. Prior therapy should have included an anthracycline unless clinically contraindicated.
- Locally advanced or metastatic non-small cell lung cancer, as first-line treatment in combination with carboplatin, in patients who are not candidates for curative surgery or radiation therapy.
- Metastatic adenocarcinoma of the pancreas as first-line treatment, in combination with gemcitabine.

In addition to the FDA-approved indications for Abraxane listed above, paclitaxel protein-bound is included as part of select FDA-approved indications for Keytruda (pembrolizumab) and Tecentriq (atezolizumab) for use in non-small cell lung cancer and triple-negative breast cancer, respectively.

The National Comprehensive Cancer Network also supports the use of Abraxane and generic taxanes in the treatment of ovarian and endometrial cancer.

NOTE: Providers and Members enrolled with Harvard Pilgrim Health Care may reference the HPHC/OncoHealth guideline located at https://oncohealth.us/medicalpolicies/harvardpilgrim/

Clinical Guideline Coverage Criteria

The plan may authorize paclitaxel protein bound for Members when **ALL** of the following criteria are met:

Metastatic Adenocarcinoma of the Pancreas

1. Documented diagnosis of advanced or metastatic pancreatic cancer

AND

2. Documentation that paclitaxel protein bound will be used in combination with gemcitabine

Endometrioid Adenocarcinoma

1. Documented diagnosis of endometrial cancer

AND

2. Documented use as a single agent

AND

3. Documentation of **one (1)** of the following:
    a. Previous treatment with paclitaxel or docetaxel was not tolerated due to documented hypersensitivity reaction, despite use of recommended pre-treatment medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine])
    b. Documented contraindication to recommended pre-treatment medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine]) such that the use of paclitaxel or docetaxel is contraindicated.

Metastatic Breast Cancer

1. Documented diagnosis of metastatic breast cancer

AND

2. Documentation of prior therapy or contraindication with an anthracycline regimen (e.g., doxorubicin, daunorubicin, epirubicin, idarubicin)

AND

3. Documentation of **one (1)** of the following:
    a. Previous treatment with paclitaxel or docetaxel that was not tolerated due to documented hypersensitivity reaction, despite use of recommended pre -treatment medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine]).
    b. Documented contraindication to recommended pre-treatment medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine]) such that the use of paclitaxel or docetaxel are contraindicated.

Non-Small Cell Lung Cancer

1. Documented diagnosis of non-small cell lung cancer

AND

2. Documentation of locally advanced unresectable or metastatic disease

AND

3. Documentation of **one (1)** of the following:
    a. First-line use in combination with Tecentriq and carboplatin **AND** non-squamous histology **AND** no EGFR or ALK genomic tumor aberrations
    b. First-line use in combination with Keytruda and carboplatin **AND** squamous histology **AND one (1)** of the following:
        i. Previous treatment with paclitaxel was not tolerated due to documented hypersensitivity reaction, despite use of recommended pre-treatment medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine])
        ii. Documented contraindication to recommended pre-treatment medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine]) such that use of paclitaxel is contraindicated
    c. Use as a single agent or in combination with carboplatin **AND** documentation of one (1) of the following:
        i. Previous treatment with paclitaxel or docetaxel was not tolerated due to documented hypersensitivity reaction, despite use of recommended pre-treatment medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine])
        ii. Documented contraindication to recommended pre-medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine]) such that use of paclitaxel or docetaxel are contraindicated

Ovarian Cancer

1. Documented diagnosis of ovarian cancer

AND

2. Documentation of **one (1)** of the following:

a. Previous treatment with paclitaxel or docetaxel that was not tolerated due to documented hypersensitivity reaction, despite use of recommended pre-treatment medications (e.g., corticosteroids, diphenhydramine and/or H-2 antagonists [e.g., famotidine, nizatidine])
b. Documented contraindication to recommended pre-medications (e.g., corticosteroids, diphenhydramine and and/or H-2 antagonists [e.g., famotidine, nizatidine])

Triple Negative Breast Cancer

1. Documented diagnosis of locally advanced unresectable or metastatic triple negative breast cancer

AND

2. Documentation of **one (1)** of the following:
   a. Use in combination with Keytruda AND PD-L1 combined positive score of at least 10 **AND**
      one (1) of the following:
      i. Previous treatment with paclitaxel was not tolerated due to documented hypersensitivity reaction, despite use of recommended pre-medications
      ii. Documented contraindication to recommended pre-medications (e.g., corticosteroids, diphenhydramine and H2 antagonists) such that the use of paclitaxel is contraindicated
   b. Use in the first-line setting in combination with Tecentriq AND PD-L1 expression of at least 1% immune cells

Off-label Use Coverage for Other Cancer Diagnoses

Coverage for other cancer diagnoses may be authorized provided effective treatment with such drug is recognized for treatment of such indication in one of the standard reference compendia, or in the medical literature, or by the Massachusetts commissioner of Insurance (commissioner) under the provisions of the "Sullivan Law": (M.G.L. c.175, s.47K).

The Plan may authorize coverage for use for other cancer diagnoses provided effective treatment with such drug is recognized as a "Medically Accepted Indication" according to the National Comprehensive Cancer Network (NCCN) Drugs and Biologics Compendium as indicated by a Category 1 or 2A for quality of evidence and level of consensus.

Note: The Plan requires prescribers to submit clinical documentation supporting the drug's effectiveness in treating the intended malignancy, including the applicable NCCN guideline(s).

In cases where the requested off-label use for the diagnosis is not recognized by the NCCN Drugs and Biologics Compendium, the plan will follow the Centers for Medicare and Medicaid Services (CMS) guidance, unless otherwise directed by the commissioner, and accept clinical documentation referenced in one of the other "Standard Reference Compendia" noted below or supported by clinical research that appears in a regular edition of a "Peer-Reviewed Medical Literature" noted below.

"Standard Reference Compendia"

1. American Hospital Formulary Service – Drug Information (AHFS-DI)
2. Thomson Micromedex DrugDex
3. Clinical Pharmacology (Gold Standard)
4. Wolters Kluwer Lexi-Drugs

"Peer Reviewed Medical Literature"

- 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 Oncology
- Leukemia
- The New England Journal of Medicine
- Radiation Oncology

When the Plan evaluates the evidence in published, peer -reviewed medical literature, consideration will be given to the following:

1. Whether the clinical characteristics of the beneficiary and the cancer are adequately represented in the published evidence.
2. Whether the administered chemotherapy regimen is adequately represented in the published evidence.
3. Whether the reported study outcomes represent clinically meaningful outcomes experienced by patients.
4. Whether the study is appropriate to address the clinical question.
    a. Whether the experimental design, in light of the drugs and conditions under investigation, is appropriate to address the investigative question (for example, in some clinical studies it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover);
    b. that non-randomized clinical trials with a significant number of subjects may be a basis for supportive clinical evidence for determining accepted uses of drugs; and,
    c. that case reports are generally considered uncontrolled and anecdotal information and do not provide adequate supportive clinical evidence for determining accepted uses of drugs.

Limitations

1. Abraxane will not be authorized in members with prior disease progression on or after treatment with Abraxane.
2. Step therapy, or first-fill requirements not required when the patient lives in or the prescribing provider's office is located in Maine for the treatment of metastatic cancer and associated conditions.

Codes

The following code(s) require prior authorization:

Table 1: HCPCS Codes

HCPCS Codes	Description
J9264	Injection, paclitaxel protein-bound particles, 1 mg
J9259	Injection, paclitaxel protein-bound particles (American Regent) not therapeutically equivalent to J9264, 1 mg
J9258	Injection, paclitaxel protein-bound particles (Teva) not therapeutically equivalent to J9264, 1 mg

References:

1. Abraxane (paclitaxel protein-bound) [prescribing information]. Summit, NJ: Celgene Corporation; 2020 August.
2. Miles D, Andre F, Gligorov J, et al. Impassion 131: phase III study comparing IL atezolizumab with paclitaxel vs placebo with paclitaxel in treatment-naïve patients with inoperable locally advanced or metastatic triple negative breast cancer (mTNBC). Annals of Oncol. 2017:28(5):V105.
3. National Comprehensive Cancer Network (NCCN). Breast cancer. V6.2024. URL: https://www.nccn.org/professionals/physician_gls/pdf/breast.pdf. Available from Internet. Accessed 2024 Dec.
4. National Comprehensive Cancer Network. Non-small Cell Lung Cancer. 11.2024. URL: https://www.nccn.org/professionals/physician_gls/pdf/nscl.pdf. Available from Internet. Accessed 2024 Dec.
5. National Comprehensive Cancer Network. Ovarian Cancer /Fallopian Tube Cancer/Primary Peritoneal Cancer. 3.2024. URL: https://www.nccn.org/professionals/physician_gls/pdf/ovarian.pdf. Available from Internet. Accessed 2024 Dec.
6. National Comprehensive Cancer Network. Pancreatic Adenocarcinoma. 3.2024. URL: https://www.nccn.org/professionals/physician_gls/pdf/pancreatic.pdf. Available from Internet. Accessed 2024 Dec.
7. Schmid P, Adams S, Rugo H, et al. Atezolizumab and nab-paclitaxel in advanced triple-negative breast cancer. N Engl J Med. 2018;379:2108-2121.
8. West H, McCleod M, Hussein M, et al. Atezolizumab in combination with carboplatin plus nab- paclitaxel chemotherapy compared with chemotherapy alone as first-line treatment for metastatic non-squamous non-small-cell lung cancer (IMpower130): a multicenter, randomized, open-label, phase 3 trial. Lancet Oncol. 2019 Jul;20(7):924-937.

Approval And Revision History

May 17, 2023: Reviewed by the Medical Policy Approval Committee (MPAC)

June 13, 2023: Reviewed by Pharmacy and Therapeutics Committee (P&T)

Subsequent endorsement date(s) and changes made:

- Originally approved September 13, 2022 by P&T and September 21, 2022 by MPAC committees effective January 1, 2023
- Administrative update: April 2023 added Medical Benefit Drugs to title, updated MATogether and RITogether fax

numbers to 617-673-0939

- May 2023 Annual Review No Change effective July 1, 2023
- Coding update per HCPCS level II quarterly release. Effective date July 1, 2023, the following HCPCS code has been added: J9259
- August 2023: Administrative update to rebrand Tufts Health Unify to Tufts Health One Care for 2024
- January 1, 2024: Administrative update: Add new J Code J9258 to Medical Necessity Guideline.
- March 12, 2024: No changes. Added Tufts Health Together to the Medical Necessity Guideline (eff 3/12/24).
- January 14, 2025: No changes (eff 1/14/25).
- November 4, 2025: Effective January 1, 2026, added limitation pertaining to patient or prescribing provider's office is located in Maine to support LD 178 - An Act Regarding Coverage for Step Therapy for Metastatic Cancer.

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.