Harvard Pilgrim Health Care | TUFTS Health Plan

Point32Health companies

Payment Policy:

# Laboratory: In Vitro Chemoresistance and Chemosensitivity Assays

Effective date: Nov. 1, 2025

**Applies to:**

**Commercial Products**

☒ Harvard Pilgrim Health Care Commercial products
☐ Tufts Health Plan Commercial products

**Public Plans Products**

☐ Tufts Health Direct – A Massachusetts Qualified Health Plan (QHP) (a commercial product)
☐ Tufts Health Together – MassHealth MCO Plan and Accountable Care Partnership Plans
☐ Tufts Health RITogether – A Rhode Island Medicaid Plan
☐ Tufts Health One Care – A dual-eligible product

**Senior Products**

☐ Tufts Health Plan Senior Care Options (SCO) (a dual-eligible product)
☐ Tufts Medicare Preferred HMO/PPO (Medicare Advantage products)

## Policy

In vitro chemotherapy sensitivity and resistance assays refer to any in vitro laboratory analysis that is performed specifically to evaluate whether tumor growth is inhibited by a known chemotherapy drug or, more commonly, a panel of drugs.

## Indications and/or Limitations of Coverage

Application of coverage criteria is dependent upon an individual's benefit coverage at the time of the request.

The following does not meet coverage criteria due to a lack of available published scientific literature confirming that the test(s) is/are required and beneficial for the diagnosis and treatment of an individual's illness.

1. In vitro chemosensitivity assays (e.g., histoculture drug response assay, fluorescent cytoprint assay) **DO NOT MEET COVERAGE CRITERIA**.
2. In vitro chemoresistance assays (e.g., extreme drug resistance [EDR] assays) **DO NOT MEET COVERAGE CRITERIA.**

## Applicable CPT/HCPCS Procedure Codes

Procedure codes appearing in policy documents are included only as a general reference tool for each policy. They may not be all-inclusive.

**Coding**

| Code | Description |
|---|---|
| 81535 | Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; first single drug or drug combination<br>Proprietary test: ChemoFX®<br>Lab/manufacturer: Helomics, Corp |
| 81536 | Oncology (gynecologic), live tumor cell culture and chemotherapeutic response by DAPI stain and morphology, predictive algorithm reported as a drug response score; each additional single drug or drug combination (List separately in addition to code for primary procedure)<br>Proprietary test: ChemoFX®<br>Lab/manufacturer: Helomics, Corp |
| 86849 | Unlisted immunology procedure |
| 88104 | Cytopathology, fluids, washings or brushings, except cervical or vaginal; smears with interpretation |

| Code | Description |
|---|---|
| 88199 | Unlisted cytopathology procedure |
| 88305 | Level IV - Surgical pathology, gross and microscopic examination |
| 88313 | Special stain including interpretation and report; Group II, all other (eg, iron, trichrome), except stain for microorganisms, stains for enzyme constituents, or immunocytochemistry and immunohistochemistry |
| 88358 | Morphometric analysis; tumor (eg, DNA ploidy) |
| 89050 | Cell count, miscellaneous body fluids (eg, cerebrospinal fluid, joint fluid), except blood; |
| 89240 | Unlisted miscellaneous pathology test |
| 0083U | Oncology, response to chemotherapy drugs using motility contrast tomography, fresh or frozen tissue, reported as likelihood of sensitivity or resistance to drugs or drug combinations<br>Proprietary test: Onco4D™<br>Lab/manufacturer: Animated Dynamics, Inc. |
| 0248U | Oncology spheroid cell culture in 3D microenvironment, 12 drug panel, brain or brain metastasis response prediction for each drug<br>Proprietary test: 3D Predict Glioma<br>Lab/Manufacturer: KIYATEC®, Inc |
| 0249U | Oncology (breast), semiquantitative analysis of 32 phosphoproteins and protein analytes, includes laser capture microdissection, with algorithmic analysis and interpretative report<br>Proprietary test: Theralink® Reverse Phase Protein Array (RPPA)<br>Lab/Manufacturer: Theralink® Technologies, Inc |
| 0285U | Oncology, disease progression and response monitoring to radiation, chemotherapy, or other systematic cancer treatments cell-free DNA, quantitative branch chain DNA amplification, plasma, reported in ng/ml<br>Proprietary test: RadTox™ cfDNA test<br>Lab/Manufacturer: DiaCarta Clinical Lab/DiaCarta Inc |
| 0435U | Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on cytotoxicity percentage observed, minimum of 14 drugs or drug combinations<br>Proprietary test: ChemoID®<br>Lab/Manufacturer: ChemoID® Lab, Cordgenics, LLC |
| 0525U | Oncology, spheroid cell culture, 11-drug panel (carboplatin, docetaxel, doxorubicin, etoposide, gemcitabine, niraparib, olaparib, paclitaxel, rucaparib, topotecan, veliparib) ovarian, fallopian, or peritoneal response prediction for each drug<br>Proprietary test: 3D PredictTM Ovarian<br>Lab/Manufacturer: KIYATEC®, Inc, KIYATEC®, Inc |
| 0564T | Oncology, chemotherapeutic drug cytotoxicity assay of cancer stem cells (CSCs), from cultured CSCs and primary tumor cells, categorical drug response reported based on percent of cytotoxicity observed, a minimum of 14 drugs or drug combinations (Reported for ChemoID®) |

## Evidence-based Scientific References


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## Publication History

03/01/2026: Annual review; administrative edits; added 0525U to coding grid
09/01/2025: Policy created to support coverage guidelines, effective for dates of service beginning Nov. 1, 2025

## Background and Disclaimer Information

This policy applies to the products of Harvard Pilgrim Health Care and Tufts Health Plan and their affiliates, as identified in the check boxes on the first page for services performed by contracted providers.

Payment is based on member benefits and eligibility on the date of service, medical necessity review, where applicable, and the provider's network participation agreement with the Plan. As every claim is unique, this policy is neither a guarantee of payment, nor a final indication of how specific claim(s) will be adjudicated. Claims payment is subject to member eligibility and benefits on the date of service, coordination of benefits, referral/authorization, and utilization management requirements (when applicable), adherence to Plan policies and procedures, and claims editing logic. An authorization is not a guarantee of payment.

Point32Health reserves the right to amend a payment policy at its discretion. CPT and HCPCS codes are updated as applicable; please adhere to the most recent CPT and HCPCS coding guidelines.

We reserve the right to conduct audits on any provider and/or facility to ensure accuracy and compliance with the guidelines stated in this payment policy. If such an audit determines that a provider/facility did not comply with this payment policy, Harvard Pilgrim Health Care and Tufts Health Plan will expect the provider/facility to refund all payments related to noncompliance.