



Payment Policy: **Drugs and Biologicals**

Point32Health companies

Applies to:

Commercial Products

- □ Tufts Health Plan Commercial products

Public Plans Products

- ☑ Tufts Health Direct A Massachusetts Qualified Health Plan (QHP) (a commercial product)

- ☑ 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

Point32Health covers medically necessary, FDA-approved drugs and biologicals and associated administration services, in accordance with the member's benefits.

Note: Drugs and biologicals outlined in this policy are covered under the member's medical benefit. Refer to the Pharmacy section of the Point32Health website for information on medications covered under the pharmacy benefit.

Injectable and Implantable Drugs must be reasonable and necessary for the diagnosis or treatment of the condition for which they are administered. Policy is in accordance with, but not limited to FDA-approved labeling, accepted compendia, manufacturer's prescribing information and/or evidence-based practice guidelines.

Drug Wastage

Practitioners, hospitals, and other providers are encouraged to care for and administer to patients in such a way that they can use drugs or biologicals most efficiently, in a clinically appropriate manner. Providers should administer medications in the most cost-effective manner, utilizing the most cost-effective vial and/or combination of vial sizes to minimize waste.

Drug wastage refers to the drug amount that is discarded and not administered to any patient.

Single-dose or single-use vial/package is intended for administration by injection/infusion and is meant for use in a single patient for a single procedure. These vials are labeled as single-dose or single-vial by the manufacturer and typically do not contain a preservative.

Multi-dose vial/package is intended for administration by injection/infusion and contains more than one dose of medication. These vials are labeled as multi-dose by the manufacturer and typically contain an antimicrobial preservative to help prevent the growth of bacteria.

General Benefit Information

Services and subsequent payment are pursuant to the member's benefit plan document. Member eligibility and benefit specifics should be verified prior to initiating services by logging on to the secure Provider portal or by contacting Provider Services.

Referral/Prior Authorization/Notification Requirements

Certain procedures, items and/or services may require referral and/or prior authorization. While you may not be the provider

responsible for obtaining prior authorization, as a condition of payment you must confirm that prior authorization has been obtained. For more information, refer to the Referral, Prior Authorization, and Notification Policy.

Provider Billing Guidelines and Documentation

Unless otherwise stated, Point32Health follows industry-standard coding guidelines. Refer to current industry standard coding guidelines for a complete list of ICD, CPT/HCPCS, revenue codes, modifiers, and their usage. Providers may only bill the procedure code(s) in accordance with the applicable financial exhibits of their provider agreements and applicable fee schedules.

Use of noncontracting labs may have the unintended consequence of subjecting the member to unnecessary services not ordered by the treating provider or other unreasonable financial exposure. In such circumstances, Point32Health may hold the ordering provider accountable for any inappropriate behavior on the part of the nonparticipating lab that has been selected.

- If the drug Unit of Service (UOS) is less than the drug quantity contained in the SUV or single-dose package, submit the administered drug quantity on one claim line and the discarded quantity on a separate claim line with the JW modifier.
- Modifier JW must be appended to a drug code packaged for single doses
- Use the appropriate HCPCS J-code(s) Bill with a count when appropriate.
- For multiple dates of service (DOS), report a separate line for each DOS with the applicable procedure code(s) and the number of units.
- Bill vaccines using the appropriate CPT 90000-series code representing the vaccine supplied.
- Providers submitting unlisted drug codes not currently covered by a HCPCS code must submit the appropriate NDC.
- Providers must append modifiers JW or JZ to single-dose vial/package claim lines for Senior Products members, in accordance with CMS.
 - Effective for DOS on or after November 1, 2024 for Commercial and Tufts Health Public Plans products, providers must append modifiers JW or JZ on all claim lines for single-dose vials/packages, as applicable. Claim lines billed without the required modifiers will deny.
 - JW: report drug waste of single-dose vial/package
 - JZ: no drug waste of a single-dose vial/package

Other Information

A valid 11-digit National Drug Code (NDC) number is required for all professional and facility claims. If a drug's NDC number has fewer than 11 digits, use leading zeros on the claim:

Illustration with numbers

Package NDC/Adding Zero/Billed NDC

1234-5678-91 = 01234-5678-91 => bill without dashes as 01234567891 12345-678-91 = 12345-0678-91 => bill without dashes as 12345067891

12345-6789-1 = 12345-6789-01 => bill without dashes as 12345678901

Unlisted Drugs

Harvard Pilgrim Health Care Commercial

Bill unlisted codes as follows:

Electronic Claim Submitters

- 837P Report the unlisted J-code in the SV101-2, loop 2400 and the NDC Number with N4 qualifier in the LIN segment, loop 2410. When reporting NDC the CTP segment is required — both CTP04 (NDC count) and CTP05 (unit of measure).
- 837I Report the unlisted J code in the SV202-2, loop 2400 and the NDC Number with N4 qualifier in the LIN segment, loop 2410. When reporting NDC in LIN segment the CTP segment is required — both CTP04 (NDC count) and CTP05 (unit of measure).

Paper Claim Submitters

- CMS-1500 form: Report the unlisted J code in 24D and units in 24G. To report NDC: In shade area of the line-item field (24A-24G), enter the N4 qualifier immediately followed by 11-digit NDC number—left justified, enter 1 space then qualifier for dispensing unit of measure followed by quantity.
- UB-04 form: Report the unlisted J code in Form Locator 44 and units in Form Locator 46. To report NDC: In Form Locator 43 enter the N4 qualifier immediately followed by 11-digit NDC number without hyphens — left justified. NDC will be followed immediately by the qualifier for dispensing unit of measure followed by quantity.

Billing Requirements for Tufts Health Public Plans

- All clinician-administered outpatient drugs (including 340B drugs) must include the 11-digit National Drug Code (NDC).
- Submit modifier UD with the 11-digit NDC code when submitting a claim for administering single-source drugs purchased under the 340B drug discount program.

Acute Hospital Carve-Out Drugs

Tufts Health Together

High-cost drugs identified on the MassHealth Acute Hospital Carve-Out Drugs List must be submitted separately from facility claims to provide appropriate compensation. Claims must include the NDC, corresponding HCPCS code(s), and number of units administered to the member. Include the following supporting documentation:

- The hospital's actual acquisition cost of the drug
- Copy of the invoice(s) for the drug from the drug manufacturer, supplier, distributor, or other similar party or agent
- Any additional supporting documentation, as necessary

Note: Claims with supporting documentation cannot be submitted electronically and must be submitted on paper.

Non-Hepatitis C Virus (HCV) High-Cost Drugs

Tufts Health Together

Claims for non-HCV high-cost drugs that have a typical treatment cost greater than \$200,000 per patient per year, an FDA orphan designation, and treat an applicable condition that affects fewer than 20,000 individuals nationwide must be billed with the procedure code and NDC, including units and unit descriptors.

Tufts Health Direct, Tufts Health RITogether and Tufts Health One Care

Claims for single-source drugs administered by providers in a health care setting must include both the HCPCS code and NDC, including units and descriptors, with the following exceptions:

- Inpatient claims
- Outpatient claims included in a bundled rate or global fee
- Claims for drugs purchased under the 340B drug discount program as designated by the Office of Pharmacy Affairs
- Claims for radiopharmaceuticals, contrast media, vaccines, or devices

Point32Health Reimburses

Providers are compensated according to the applicable network contracted rates and applicable fee schedules.

- The provision of injectable and implantable non-self-administered drugs that must be administered by the provider.
- Listed and unlisted drugs at a rate that will not exceed Point32Health's drug fee schedule allowable amounts. The drug fee schedule is periodically updated based on Average Sale Price (ASP), Average Wholesale Price (AWP), Specialty Pharmacy Programs, and/or Medicare/Medicaid regulations, as applicable.
- FDA-approved drugs
- Drug wastage in the following circumstances:
 - Single-dose vials/packages: discarded drugs along with the amount of the drug administered (Note: any amount billed as a discarded drug cannot be administered to another patient)
 - Multi-dose vials: amounts administered to the patient
 - Pharmaceutical waste and unused portions of any single-use vial/package when the wasted medication is documented in the patient's medical record, including the name of the clinician wasting the pharmaceutical, date/time, amount of wasted pharmaceutical, and national drug code (NDC) number
 - Note: This policy applies to both professional and facility claims.

Point32Health Does Not Reimburse

- Drugs/biologicals billed without a valid NDC. The NDC must match the billed revenue or procedure code, whether listed
- Drugs and vaccines supplied by pharmacy prescription
- Drugs related to the treatment of a non-covered service
- Drug wastage in the following circumstances:
 - Multi-dose vial medication that is discarded/wasted or not otherwise administered to the patient.
 - Discarded drugs if none of the drug was administered to the patient.
 - Drugs billed with modifier JW (drug amount discarded/not administered to any patient) when another claim line does not exist for the same drug on the same DOS.

- Contaminated pharmaceuticals
- Drug waste billed without supporting documentation in the member's medical record.
- Drugs that are billed without using the most appropriate size vial or combination of vials to deliver the administered dose (see example below)

Example:

Drug waste when an inappropriate vs. an appropriate size or combination of vials is submitted to deliver the administered dose.

- J9035 (bevacizumab [Avastin]), 10mg/unit
- Prescribed dose: 10mg/kg x Pt weight (86kg) = 860mg
- Available in two dosage forms and strengths: 100mg/4ml (SUV) or 400mg/16ml (SUV)

Inappropriate vial combination

3 (400mg vials) = 1200mg utilized to yield the prescribed dose (860mg)

340mg wastage

Most appropriate vial combination

2 (400mg vials) + 1 (100mg vial) = 900mg utilized to yield the prescribed dose (860mg)

40mg wastage

Related Policies and Resources

Payment Policies

Harvard Pilgrim

- Chemotherapy Oncology
- Home Infusion
- Laboratory & Pathology
- Radiation Oncology
- Vaccines and Immunizations

Tufts Health Plan

- Chemotherapy Oncology
- Home Infusion
- Laboratory and Pathology
- Radiation Oncology
- Vaccines and Immunizations

Clinical and Pharmacy Resources

- Medical Benefit Drug Medical Necessity Guidelines
- Pharmacy Medical Necessity Guidelines
- **Utilization Management for Pharmacy**

Publication History

October 2024: Created combined policy to support existing billing requirements and claims processes

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.