

Injectable and Implantable Outpatient Drugs

Policy

Harvard Pilgrim reimburses contracted providers for the provision of covered injectable and implantable non-self-administered drugs in an outpatient setting.

Policy Definition

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.

Prerequisite(s)

Applicable Harvard Pilgrim referral, notification and authorization policies and procedures apply. (Refer to [Referral, Notification and Authorization](#) for more information.)

HMO/POS/PPO

A referral is required for specialist services for HMO and in-network POS members.

Open Access HMO and POS

For [Open Access HMO and Open Access POS](#) products, no referral is required to see a contracted specialist.

Harvard Pilgrim Reimburses¹

HMO/POS/PPO

- The provision of injectable and implantable non-self-administered drugs that must be administered by the provider.
- Injectable/implantable medications may not be dispensed at retail/mail pharmacies, except those noted below. (Refer to list of "Pharmacy Prescription Exceptions" below.)
- Listed and unlisted drugs at a rate that will not exceed Harvard Pilgrim's drug fee schedule allowables. Harvard Pilgrim's drug fee schedule is periodically updated based on Average Sale Price (ASP), Average Wholesale Price [AWP], Harvard Pilgrim Specialty Pharmacy Program, or Medicare.
- FDA-approved drugs only.
- Drugs related to contraception, if the member has the birth control rider.

Pharmacy Prescription Exceptions

The non-self-administered medications listed below may be obtained at participating retail pharmacies, for members 19+. Other age restrictions may apply.²

- | | | | |
|---------------------------|--------------|-----------------------------|----------------------|
| • Adacel TDAP | • Flulaval | • Medroxyprogesterone 150mg | • Quadracel DTAP-IPV |
| • Afluria | • Fluzone | • Menactra | • Recombivax HB |
| • Bexsero | • Gardasil 9 | • Menquadfi | • Shingrix |
| • Boostrix TDAP | • Havrix | • Methotrexate Injection | • TDvax |
| • Depo-Provera 400mg | • Hepilisav | • M-M-R II Vaccine | • Tenivac |
| • Depo-SQ Provera 104mg | • Hyperrab | • Menveo | • Trumenba |
| • Dexamethasone injection | • Imogam | • Naloxone injection | • Twinrix |
| • Engerix-B | • Imovax | • Pneumovax 23 | • Vaqta |
| • Flud | • Kedrab | • Prevna 13 | • Varivax Vaccine |
| • Flublok | • Kinrix | • Proquad | • Vivitrol |
| • Flucelvax | | | • Zostavax |

Harvard Pilgrim Does *Not* Reimburse

HMO/POS/PPO

- Anabolic steroids when used for performance enhancement.
- Drug/Biologicals billed without a valid NDC number
- Drug/Biologicals when the NDC number does not match to the billed revenue, HCPCS or CPT code
- Drug/Biologicals when the unlisted J code does not match to the billed NDC number
- Drugs and vaccines supplied by pharmacy prescription (Refer to pharmacy prescription exceptions.)
- Drugs related to the treatment of a non-covered service
- Experimental use of botulinum toxin A and botulinum toxin Type B will not be approved
- CPT 27412 (autologous chondrocyte implantation, knee) and HCPCS code J7330 (autologous cultured chondrocytes, implant) has not also been billed for the same date of service by any provider.
- CPT 58300 (Insertion of intrauterine device [IUD] or any intrauterine device has not also been billed for the same date of service by any provider.
- CPT J7307 (Etonogestrel implant system) when billed and the associate drug delivery insertion code (CPT 11981 or 11983) has not also been billed for the same date of service by any provider.

Member Cost-Sharing

Services subject to applicable member out-of-pocket cost (e.g., copayment, coinsurance, deductible).

Provider Billing Guidelines and Documentation

Coding³

Code	Description	Comments
J0585	Onabotulinumtoxin–A (Botox)	Experimental use of Onabotulinumtoxin–A, Rimabotulinumtoxin–B, Abobotulinumtoxin–A and Incobotulinumtoxin–A will not be approved.
J0586	Abobotulinumtoxin–A (Dysport)	
J0587	Rimabotulinumtoxin–B (Myobloc)	
J0588	Incobotulinumtoxin–A (Xeomin)	

Other Information

Harvard Pilgrim Healthcare requires that a valid National Drug Code (NDC) number for all professional claims and all facility claims, except inpatient facility claims.

The NDC is a universal number that identifies a drug. The NDC number consists of 11 digits in a 5-4-2 format. The first five digits identify the manufacturer of the drug and are assigned by the Food and Drug Administration. The remaining digits are assigned by the manufacturer and identify the specific product and package size.

Some packages will display fewer than 11 digits, but leading zeroes can be assumed and need to be used when billing. For example:

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

- Use the appropriate Level II HCPCS (J) billing code(s). Bill with a count when appropriate.

- For multiple dates of service report a separate line for each date of service with the applicable procedure code(s) and the number of units.
- Bill vaccines using the appropriate CPT 90000 series code representing the vaccine supplied.

Unlisted Drugs

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.

Related Policies

Payment Policies

- Billing Requirements for Outpatient Revenue Codes
- Drug Wastage
- Gynecology
- Home Infusion Therapy
- Oncology and Chemotherapy
- Vaccine and Immunization

Billing & Reimbursement

- Claims Submission Guidelines

Referral, Notification & Authorization

- Prior Authorization Policy

PUBLICATION HISTORY

10/01/01	original documentation
08/01/03	effective 08/01/03 listed and unlisted drug reimbursement not to exceed Harvard Pilgrim drug fee schedule or Specialty Pharmacy Program rates; added billing unlisted J codes
04/30/04	authorization and reimbursement sections modified
01/31/06	annual review and coding update; listed Botox covered diags
01/31/07	annual review and coding update; additional covered diags for Myobloc; Gardasil and Dexamethasone injection as pharm script exceptions; NDC for UB billing of unlisted J codes
01/31/08	annual review; edited Botox covered diags; minor edits
10/31/08	added experimental use of botulinum toxin A and botulinum toxin Type B will not be approved
01/31/09	annual review and coding update; edited Botox covered diags, clarified paper UB-40 claim submission, added ASP reference
05/15/09	clarification of covered Botox diags
11/15/09	annual review; no changes

PAYMENT POLICIES

01/15/10	annual coding update; edited botox description
03/15/10	added Cervarix to pharmacy prescription exceptions
11/15/10	annual review; no changes
01/01/12	removed First Seniority Freedom information from header
01/15/12	annual coding review; removed covered dx's from botox codes and added new botox code
11/15/12	annual review; minor edits
11/15/13	annual review; administrative edits
06/15/14	added <i>Connecticut Open Access HMO</i> referral information to Prerequisites
11/15/14	annual review; no changes
11/15/15	annual review; added Naloxone to pharmacy exceptions, updated billing for unlisted drugs, added NDC information
02/15/16	added Botulinum A and B toxin Medical Policy as a related policy
11/15/16	annual review; removed drugs from pharmacy exceptions and Botox
11/15/17	annual review; no changes
01/01/18	added report multiple dates of service on a separate line; updated Open Access Product referral information under Prerequisites
11/01/18	annual review; updated pharmacy exceptions list; updated related policies; administrative edits
04/01/19	update to pharmacy exceptions
11/01/19	annual review; updated Harvard Pilgrim Does Not Reimburse, added NDC required effective 01/01/20 to Other Information; added Drug Wasted Payment Policy to Related Policies
06/01/20	edited Policy Definition, added HPHC does not reimburse certain codes when the associated code(s) has not been billed
11/02/20	annual review; administrative edits; updated pharmacy exception list
11/01/21	annual review, administrative edits, updated related policies

¹This policy applies to the products of Harvard Pilgrim Health Care and its affiliates—Harvard Pilgrim Health Care of Connecticut, Harvard Pilgrim Health Care of New England, and HPHC Insurance Company—for services performed by contracted providers. Payment is based on member benefits and eligibility, medical necessity review, where applicable, and provider contractual agreement. Payment for covered services rendered by contracted providers will be reimbursed at the lesser of charges or the contracted rate. (Does not apply to inpatient per diem, DRG, or case rates.) HPHC reserves the right to amend a payment policy at its discretion. CPT and HCPCS codes are updated annually. Always use the most recent CPT and HCPCS coding guidelines.

²This list is subject to change.

³The table may not include all provider claim codes related to injectable and implantable outpatient drugs.