Drugs and Biologicals Payment Policy

Applicability

This Policy applies to the following Fallon Health products:

☒ Fallon Medicare Plus, Fallon Medicare Plus Central (Medicare Advantage)
☒ MassHealth ACO
☒ NaviCare HMO SNP
☒ NaviCare SCO (Medicaid-only)
☒ Summit Eldercare PACE
☒ Fallon Health Weinberg PACE
☒ Community Care (Commercial/Exchange)

Policy

This policy applies to payment for medically necessary drugs and biologicals that are covered under the medical benefit (i.e., non self-administered drugs and biologicals). Medical benefit drugs are typically administered as an injection or infusion in a physician's office, clinic or hospital, and may also be administered in a member's home.

FDA-approved drugs and biologicals are considered medically necessary when safety, efficacy and established clinical benefit have been demonstrated in the peer-reviewed published literature or when the drug or biological is listed in one of the standard reference compendia as safe and effective for the prescribed indication. The U.S. Food and Drug Administration (FDA) approves drugs and biologicals for specific indications that are included on the product's labeling. When a drug is used for an indication other than one specifically included in the labeling, it is referred to as an off-label use. Many off-label uses are effective, well-documented in the literature, and widely used. Good medical practice and the best interests of the patient require that physicians use legally available drugs and biologics according to their best knowledge and judgement. If physicians use a product for an indication not in the approved labeling, they have the responsibility to be well informed about the product, to base its use on firm scientific rationale and on sound medical evidence, and to maintain records of the product's use and effects. Use of a marketed product in this manner when the intent is the "practice of medicine" does not require the submission of an Investigational New Drug Application (IND) or review by an Institutional Review Board (IRB). However, the institution at which the product will be used may, under its own authority, require IRB review or other institutional oversight (FDA, "Off-Label" and Investigational Use Of Marketed Drugs, Biologics, and Medical Devices, Content Current as of: 05/02/2020).

The investigational use of approved, marketed products differs from the situation described above. "Investigational use" suggests that evidence supporting the safety, efficacy and/or established clinical benefit for the off-label indication are lacking. Such use of drugs and biologics is considered not medically necessary. Investigational use of drugs and biologicals may be covered in the context of an approved or qualified clinical trial – see Clinical Trials Payment Policy for additional information.

Medical Benefit drugs and biologicals are sometimes referred to as "physician/clinician-administered drugs." Physician/clinician-administered drugs include both injectable and noninjectable drugs and biologicals that are typically administered by medical professionals in physicians' offices, clinics, or hospitals. Section 6002 of the Deficit Reduction Act (DRA) of 2005 added section 1927(a)(7) to the Social Security Act, requiring State Medicaid programs to collect manufacturer rebates for Physician-Administered Drugs. Prior to the DRA, most States did not collect rebates on physician-administered drugs because claims typically did not contain the NDCs which are necessary for the State to invoice drug manufacturers for rebates. Physician-Administered Drugs must be identified on a claim by a HCPCS Code, National Drug Code (NDC), NDC Qualifier and NDC Quantity. Fallon Health is contractually obligated to ensure that valid NDCs are included on claims for physician-administered drugs in order to facilitate the collection of manufacturer rebates for the Massachusetts Medicaid Program (MassHealth). The Social

Security Act specifically exempts vaccines from the rebate requirement and therefore vaccines are excluded from the NDC reporting requirement for physician-administered drugs and biologicals.

Reimbursement

The Plan will reimburse contracted providers for the provision of medically necessary covered drugs and biologicals. Some drugs and biologicals require prior authorization. See **Referral/notification/prior authorization requirements** below.

Providers should administer drugs and biologicals in the most cost-effective and clinically appropriate manner. Plan reimbursement is for drugs and biologicals which are administered to a Plan member, only up to the next incremental Level II HCPCS code unit.

The Plan does not reimburse for that portion of a multi-use vial of medication that is not administered to Plan members including, but not limited to, those that are determined to be contaminated, wasted, or unused, unless documentation within the patient's medical record file indicates the date, time, and name of clinical staff who wasted the portion of medication within a single-use vial. Providers will utilize the most appropriate sized single-use vial or combination of single-use vials to deliver the ordered dose of medication and minimize waste. Reimbursement will be made for discarded portions of single-use vials only when proper billing guidelines are followed as outline in the Billing/Coding section of this policy.

Reimbursement for drugs and biologicals will be made in accordance with the provider's contract.

Effective December 1, 2018 this policy will be applicable to inpatient facilities excluding payments made as part of a Diagnosis Related Group (DRG) methodology.

Referral/notification/prior authorization requirements

The ordering physician is required to obtain prior authorization for those drugs and biologicals that require prior authorization. The list of drugs and biologicals that require prior authorization is available in the Pharmacy prior authorizations section of the Plan website.

Effective October 1, 2024, Prime Therapeutics Management, LLC (Prime) will review prior authorization requests for physician-administered drugs (medical benefit drugs) for Fallon Health members provided in place of service 11, 12, 19 and 22, Prior authorization requests can be submitted to Prime through Prime's electronic portal at gateway.pa.com. If the electronic portal is inaccessible, prior authorization forms can also be faxed to 1-888-656-6671. For more information about prior authorizations, providers can call Prime at 1-800-424-1740. General questions regarding the medical pharmacy program may be directed to Fallon at 1-866-275-3247, prompt 5, or by email at askfchp@fallonhealth.org.

For medical benefit drugs administered in POS other than 11, 12, 19 and 22, the prior authorization request must be submitted to Fallon Health. Providers may submit prior authorization request to Fallon Health electronically, via fax and by regular mail. Fallon Health will also accept requests for prior authorization by telephone.

PACE (Summit Eldercare PACE, Fallon Health Weinberg PACE)

Each PACE plan member is assigned to an Interdisciplinary Team. PACE provides participants with all the care and services covered by Medicare and Medicaid, as approved by the interdisciplinary team, as well as additional medically necessary care and services not covered by Medicare and Medicaid. With the exception of emergency care and out-of-area urgently needed care, all care and services provided to PACE plan members must be approved by the interdisciplinary team.

Billing/coding guidelines

Drugs and biologicals are identified on a professional claim (CMS 1500 or electronic equivalent) by an HCPCS code, and on a facility claim (UB-04 or electronic equivalent) by a revenue code and HCPCS code combination. If a drug does not have a unique HCPCS code, please assign the appropriate unlisted/not otherwise classified (NOC) HCPCS code.

Payment Rules for Post-Service Claims Edit (PSCE) Drugs

Drugs with a post-service claims edit (PSCE) will require an appropriate ICD-10 diagnosis attached to the claim for payment. The claim must also meet the appropriate frequency and unit quantity for payment. This list can be found in the Medical Benefit Drug Search section of the Plan's website. See link below:

https://fm.formularynavigator.com/FormularyNavigator/DocumentManager/Download?clientDocumentId=q0rFBp8AKkCU0tq0MP4Vhw.

National Drug Code (NDC) and 340B-Acquired Drugs Reporting Requirements

The NDC is a universal number that identifies a drug. When reporting an NDC, all of the following "NDC Information" is required:

- NDC Qualifier (F4)
- 11-digit NDC
- NDC Unit of Measure Qualifier (F2, GR, ME, UN, ML)
- NDC quantity

To access the National Drug Code Directory published by the U.S. Food and Drug Administration, go to: National Drug Code Directory | FDA.

The Centers for Medicare and Medicaid Services (CMS) contractor for Pricing, Data Analysis and Coding (PDAC) also maintains an NDC to HCPCS Crosswalk that is updated monthly: PDAC - NDC/HCPCS Crosswalk.

NDC Unit of Measure Qualifiers	
Qualifier	**Description**
F2	International unit (for example, anti-hemophilia factor)
GR	Gram (for creams, ointments and bulk powder)
ME	Milligrams (for creams, ointments and bulk powder)
UN	Unit (for tablets, capsules, suppositories and powder-filled vials)
ML	Milliliters (for liquids, suspensions and lotions)

For Fallon Medicare Plus, Fallon Medicare Plus Central and Community Care members, Fallon Health requires NDC Information, for all unlisted/not otherwise classified HCPCS codes including but not limited to: A9699, J3490, J3590, J7599, J7699, J7799, J7999, J8498, J8499, J8597, J8999, J9999 and C9399. Claims for unlisted/not otherwise classified HCPCS codes submitted without valid NDC Information will be denied. Claims may be resubmitted with the required NDC information. Timely filing and claim reconsideration requirements will need to be followed when resubmitting denied claims.

Additionally, for Fallon Medicare Plus, Fallon Medicare Plus Central, NaviCare HMO SNP, Summit ElderCare PACE and Fallon Health Weinberg PACE members, all 340B covered entities including hospital-based and non-hospital-based entities, that submit claims for separately payable Part B drugs and biologicals are required to report modifier JG or TB, as appropriate, on claim lines for drugs acquired through the 340B program for claims with dates of service January 1, 2024 through December 31, 2024. For claims with dates of service on or after than January 1, 2025, all 340B covered entities, including hospital-based and non-hospital-based entities, that submit claims for separately payable Part B drugs and biologicals, must report the TB modifier on claim lines for drugs acquired through the 340B program.

Medicare 340B Modifiers	
Modifier	**Description**
JG	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes (terminated 12/31/2024)
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes for select entities

For MassHealth ACO, NaviCare HMO SNP (dual eligible Medicare and Medicaid), NaviCare SCO (Medicaid-only), and Summit ElderCare plan members, to ensure MassHealth regulatory compliance, Fallon Health requires valid NDC Information (including NDC unit of measure and quantity) for clinician-administered drugs, for the following types of claims:

- All claims with drug HCPCS codes, regardless of revenue code or billed amount drugs must have a corresponding NDC.
- NDC information is required for clinician-administered drugs billed with revenue code 025X, when a single drug amount is equal to or greater than $10,000. If multiple drugs are combined on a revenue 025X claim line and the total billed is equal to or greater than $10,000, the provider must split the claim lines so that no single claim line for 025X drugs is equal to or greater than $10,000.
- Any claim line for a single-source drug (as defined in 42 CFR § 447.502) or any drug listed under 1927(a)(7)(B)(i) of the Social Security Act as a "Top 20 Multiple Source Covered Outpatient Physician Administered Drug" as listed by CMS requires an NDC regardless of billed amount or revenue code.

Additionally, for MassHealth ACO and NaviCare SCO plan members, acute outpatient hospitals, community health centers and physicians billing for clinician-administered outpatient drugs are required to report modifier UD to identify a 340B-acquired drug.

MassHealth 340B Modifier	
Modifier	**Description**
UB	Drug or biological purchased through 340B program

MassHealth Acute Hospital Carve-Out Drugs

MassHealth maintains lists of Acute Hospital Adjudicated Payment Amount per Discharge (APAD) and Adjudicated Payment per Episode of Care (APEC) carve-out drugs. The list currently comprises CAR T-cell and gene therapies. The MassHealth Acute Hospital Carve-Out Drug List is available at: https://mhdl.pharmacy.services.conduent.com/MHDL/.

In accordance with MassHealth Managed Care Entity Bulletin 125 (March 2025), effective April 1, 2025, Fallon Health will transition the review and management of all APAD and APEC carve-out drugs to the MassHealth Drug Utilization Review (DUR) Program. Effective for dates of services on or after April 1, 2025, all prior authorization (PA) requests for APAD and APEC carve-out drugs must be submitted to the DUR Program for review and approval before administration. MassHealth will pay these claims directly for MassHealth ACO members consistent with Sections 5.B.8.b and 5.C.9 of the current MassHealth Acute Hospital Request for Applications (Acute Hospital RFA) for in-state acute hospitals and regulations at 130 CMR 450.233(D) for out-of-state acute hospitals. This change centralizes oversight to ensure appropriate utilization, enhance prior authorization efficiency, and streamline payment processes.

Note: Only the APAD and APEC carve-out drugs themselves will be reviewed by the MassHealth DUR Program and reimbursed by MassHealth. Fallon Health will continue to review prior authorization requests and pay claims for the professional and facility services related to the APAD and APEC carve-out drugs.

For additional information, acute inpatient and outpatient hospitals may refer to MassHealth Acute Inpatient Hospital Bulletin 201 (March 2025) and MassHealth Acute Outpatient Hospital Bulletin 41 (March 2025), respectively.

For Providers Submitting Paper Claims

CMS-1500 form:

Bill both the HCPCS J code and NDC number in field 24D, please enter the NDC number under the Level II HCPCS code, bill units in field 24G.

To enter supplemental information, begin at 24A by entering the qualifier and then the information. Do not enter a space between the qualifier and the number/code/information. Do not enter hyphens or spaces within the number/code.

Additional information for reporting NDC:

- When entering supplemental information, add in the following order: qualifier, NDC code, one space, unit/basis of measurement qualifier, quantity.
- The number of digits for the quantity is limited to eight digits before the decimal and three digits after the decimal. If entering a whole number, do not use a decimal. Do not use commas. (Examples: 1234.56, 2, 99999999.999)
- When a dollar amount is being reported, enter the following after the quantity: one space, dollar amount. Do not enter a dollar sign.

UB-04 form:
Bill the Level II HCPCS code in field locator 44, the NDC number in field locator 43 and service units in field locator 46.
When required to submit NDC drug and quantity information for Medicaid rebates, submit the NDC code in the red shaded portion of the detail line item in positions 01 through 13. The NDC is to be preceded with the qualifier N4 and following immediately by the 11 digit NDC code (e.g. N499999999999). Report the NDC quantity in positions 17 through 24 of the same red shaded portion. The quantity is to be preceded by the appropriate qualifier (UN, F2, GR or ML) There are six bytes available for quantity. If the quantity is less than six bytes, left justify and space-fill the remaining positions (e.g., UN2 or F2999999).

Drug Waste

The Plan reserves the right to audit to verify payment accuracy. Neither the Plan nor Plan members can be held financially responsible for any denied payments for drugs and biologicals that were not administered.

- For multi-use vials, bill only for the portion of the medication administered to the member; wasted pharmaceutical will not be reimbursed.
- Plan reimbursement is for drugs and biologicals which are administered to a Plan member, only up to the next incremental Level II HCPCS code unit. Wasted medication from a single-use vial will be reimbursed when the wasted medication is documented as such within the patient's medical record. Such documentation should include the date, time, and name of the clinical staff wasting the medication, as well as the amount wasted. Documentation of waste must be retained within the patient's medical record and/or made available to Plan audit representatives upon request.
- Providers will administer drugs to members in such a way that they can use the drugs most efficiently, in a clinically appropriate manner. Providers will utilize the most appropriate sized single-use vial or combination of single-use vials to deliver the ordered dose of medication and minimize waste.

Medical Drug Wastage Program

This program focuses on therapeutically appropriate, and cost-effective dose optimization of certain weight-based or body surface area (BSA) based infused medications. Fallon requires dose rounding (i.e. reduction) for infused drug products to the nearest lowest vial size if within 10% of the original prescribed dose. Providers must comply with this policy or otherwise request as part of prior authorization medical necessity for higher dosing. See the Drug Wastage Program document for comprehensive list of applicable drug products and details.

For Medicare Advantage, NaviCare HMO SNP and PACE Plan Members

Effective January 1, 2017, CMS requires the use of the JW modifier on claims for all separately payable Part B with discarded drug amounts from single-dose containers, and requires that providers document the amount of discarded drugs in the member's medical record. The Plan does not compensate for any drug billed with modifier JW unless another claim line for the same drug is billed on the claim.

Effective January 1, 2023, the JZ modifier will be accepted but not be required when billing for separately payable Part B drugs designated as single-dose container on the FDA-approved label or package insert for which there are no discarded amounts. Effective for dates of service on or after July 1, 2023, claims for separately payable Part B drugs designated as single-dose container on the FDA-approved label or package insert that do not report the JW or JZ modifier

on may be subject to provider audits. Effective October 1, 2023, claims that do not report the JW or JZ modifiers as appropriate, will be denied.

Modifier	Description
JW	Drug amount discarded/not administered to any patient
JZ	Zero drug amount discarded/not administered to any patient

Billing for No Cost Drugs and Biologicals

Physicians and nonphysician practitioners (NPPs) who bill independently should not report no cost drugs and biologicals as there are no system edits in place that require them to do so and there is no field on the professional claim form to report a non-covered charge. There is one exception: the administration of state-supplied vaccines. For the administration of state-supplied vaccines, physicians and NPPs should:

- Submit the appropriate immunization administration CPT code (90460-90461 or 90471-90474) in addition to the vaccine/toxoid CPT code, and
- Attach the SL modifier to the vaccine/toxoid CPT code with a charge of $0.00 to indicate that the vaccine/toxoid was state-supplied.

Some billing systems require that a charge be reported, even for drugs and biologicals for which the physician or NPP incurs no cost. In that case, the physician or NPP may submit a token charge of less than $1.01 for the item in the Covered Charges field of the CMS-1500.
Generally, hospitals are not required to report no cost drug or biologicals, however there are situations where no cost drugs and biologicals may be reported on claims:

- For hospitals paid under the Medicare hospital Outpatient Prospective Payment System (OPPS), when a drug is provided at no cost (for example, a specialty pharmacy drug, or a drug supplied at no cost by a clinical trial sponsor), claims processing edits may prevent drug administration charges from being paid when the claim does not contain a covered/billable drug charge. Therefore, for drugs and biologicals provided at no cost in a hospital outpatient department, providers should report the HCPCS code for the drug or biological with appropriate units and a token charge of less than $1.01 for the item in the Covered Charges field and mirror this less than $1.01 amount in the Non-Covered Charge field.
- For hospitals reimbursed by other payment methodologies, if it is necessary for a hospital to report a charge for drugs and biologicals for which the hospital incurs no cost, for example, because the hospital's billing system requires that a charge be reported on the UB-04, the hospital may report the drug or biological with appropriate units and a token charge of less than $1.01 for the item in the Covered Charges field and mirror this less than $1.01 amount in the Non-Covered Charge field.

Home Infusion Drugs

For Medicare members, providers must adhere to CMS requirements for billing home infusion drugs that are covered under Part D: http://www.fchp.org/providers/pharmacy/online-drug-formulary.aspx.

Ophthalmologic Avastin (bevacizumab)

Claims (professional and facility) for bevacizumab for ophthalmologic indications should be submitted using HCPCS code J9035 (injection, bevacizumab, 10 mg), bill one unit per eye.

There is one exception: outpatient hospitals and ambulatory surgical centers reimbursed under Medicare OPPS or ASC payment methodology use HCPCS code C9257 (injection, bevacizumab, 0.25 mg) to report ophthalmologic bevacizumab.

The Plan will not require Invoices for ophthalmologic bevacizumab effective for dates of service on or after October 1, 2021.

Place of service

This policy applies to services rendered in the outpatient and inpatient setting.

Policy history

Origination date:	11/1/09
Previous revision date(s):	07/01/2010 – updated language in the Policy, Reimbursement and Billing/coding guidelines sections to indicate policy and process regarding pharmaceutical waste. 01/01/2012 - Updated billing/coding guidelines to add discussion about revenue code 0636. 05/01/2012 - Removed requirement for itemized invoice with revenue code 0636. 11/1/2012 – Removed requirement to submit modifier JW - drug amount discarded and that the amount discarded from single-use vial drugs will not be reimbursed. 02/01/2013 – Updated NDC billing requirements for members enrolled through MassHealth. 09/01/2013 - Updated discussion of drug waste and reimbursement for multi vs. single use vials. 07/01/2014 - Clarified discussion about drug waste. 11/01/2015 - Moved to new Plan template and updated Exhibit A. 11/01/2016 - Annual review, no changes were made to Exhibit A per MassHealth. Still no CMS guidance on NDC requirements for radiopharmaceuticals. 03/01/2017 - Updated prior authorization requirements section. 05/01/2017 - Added JW modifier update.
Connection date & details:	November 2017 – Added implantable definition and updated Exhibit A with most recent listing from MassHealth. April 2018 – Clarified JW modifier billing requirements October 2018 – Policy is now applicable to in-patient services, policy name changes from Outpatient Drugs to Drugs and Biologicals. April 2019 – Updated addendum A for clarifying PA requirements and removing termed codes. July 2019 - Added Unit of Measurement requirements to Billing/Coding Guidelines for Masshealth and NaviCare October 2019 – Clarified billing guidelines, added Table B medical drug criteria. January 2020 – Updated Masshealth NDC exlusions and Table A required codes. June 2020 – Added Post Service Claims Edit (PSCE) description and removed Appendix B medical drug criteria as it will now be posted on the Fallon medical benefit drug lookup and updated monthly. Removed Exhibit A. October 2020 – Clarified NDC requirements for physician-administered drugs, added information about billing for MassHealth Carve-Out Drugs. January 2021 – Added information about billing for no cost drugs and biologicals; documented existing requirement specific to billing for home infusion drugs under Medicare Part D. April 2021 – Added information about NDC-HCPCS validation for MassHealth ACO and NaviCare members; clarified billing requirements for 340B drugs. October 2021 – Updated to include billing information for ophthalmologic Avastin (bevacizumab). January 2023 – Under Referral/notification/prior authorization requirements, clarified that for medical benefit drugs administered in POS other than 11, 12, 19 and 22, the prior

authorization request must be submitted to Fallon Health; added instructions for use of the JW and JZ modifier under Billing/coding guidelines, clarified that modifier UD must be reported on claims for physician/clinician-administered outpatient drugs acquired under the 340B program.
July 2024 – Updated Billing/coding guidelines to include new section on Drugs Designated for Exclusion from 340B Coverage.
January 2025 – Updated to reflect Magellan Rx rebrand to Prime Therapeutics Management effective October 1, 2024; added new paragraph for Medical Drug Wastage Program under Billing/coding guidelines; under Billing/coding guidelines updated to indicate that effective January 1, 2025 Medicare is requiring that all 340B drugs are submitted with modifier JB. Modifier JG is being discontinued effective 12/31/2024.
April 2025 – Under Billing/coding guidelines, removed section Drugs Designated from 340B Coverage for MassHealth ACO members (no longer applicable), updated MassHealth Acute Hospital Carve-Out Drugs section, by deleting all previous content and replacing it with new guidance from MassHealth effective April 1, 2025.

The criteria listed above apply to Fallon Health plan and its subsidiaries. This payment policy has been developed to provide information regarding general billing, coding, and documentation guidelines for the Plan. Even though this payment policy may indicate that a particular service or supply is considered covered, specific provider contract terms and/or member individual benefit plans may apply and this policy is not a guarantee of payment. The Plan reserves the right to apply this payment policy to all of the Plan companies and subsidiaries. The Plan routinely verifies that charges billed are in accordance with the guidelines stated in this payment policy and are appropriately documented in the medical records. Payments are subject to post-payment audits and retraction of overpayments.