

Drugs and Biologicals Payment Policy

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-administered drugs." Physician-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 January 1, 2020, Magellan Rx Management 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 Magellan through Magellan's electronic portal at ih.magellanrx.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 Magellan Rx Management 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 Payment Rules for Post-Service Claims Edit (PSCE) Drugs.

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.

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.

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>.

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.

National Drug Code (NDC) Requirements for Physician-Administered Drugs

Note: Physician-administered drugs may also be referred to as clinician-administered drugs.

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)

1. **For commercial and Medicare plan 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 submitted without a valid NDC 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.
 - a. Additionally, for Medicare plan members, providers billing for physician-administered outpatient drugs are required to report modifier JG or TB, as appropriate, to identify a 340B-acquired drug.

Medicare 340B Modifiers	
Modifier	Description
JG	Drug or biological acquired with 340B drug pricing program discount
TB	Drug or biological acquired with 340B drug pricing program discount, reported for informational purposes

2. **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) on claims for physician-administered outpatient drugs, including 340B drugs (but not including vaccines).
 - a. Additionally, for MassHealth ACO and NaviCare SCO plan members, providers billing for physician-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

Effective for dates of service on or after July 1, 2021, claims for physician-administered drugs for MassHealth ACO and NaviCare plan members will be denied if the NDC does not match the HCPCS code being billed.

- Generally, physician-administered drugs include both injectable and non-injectable drugs and biologics administered in an office, outpatient or clinic setting.
- The NDC can be found on the drug package. If there is more than one NDC used with a HCPCS code (for example, when multiple strengths are used), submit each NDC as a separate claim line.
- Each HCPCS and/or revenue code submitted for physician-administered drugs must have a corresponding NDC.
- Claims submitted with revenue codes starting with the digits “63” (e.g., 63x) or 343 or 344 must include a HCPCS code and NDC information (i.e., valid NDC, unit of measure and quantity).
- NDC information is not required for physician-administered drugs billed with revenue code 025X, except 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.
- Claims submitted without a valid NDC will deny. Claims submitted without the required NDC information will deny. Claims may be resubmitted with the required NDC information. Timely filing and claim reconsideration requirements will need to be followed when resubmitting denied claims.

Drugs Designated for Exclusion from 340B Coverage

Effective for dates of service on or after July 1, 2024, MassHealth has designated the following eleven drugs as nonpayable when purchased through the 340B drug pricing program and provided to MassHealth ACO members:

- Abecma (idecabtagene vicleucel) (HCPCS code Q2055)
- Breyanzi (lisocabtagene maraleucel) (HCPCS code Q2054)
- Carvykti (ciltacabtagene autoleucel) (HCPCS Code Q2056)
- Hemgenix (etranacogene dezaparvovec) (HCPCS code J1411)
- Kymriah (tisagenlecleucel) (HCPCS code Q2042)
- Luxturna (voretigene neparvovec) (HCPCS code J3398)
- Skysona (elivaldogene autotemcel) (HCPCS code J3490/J3590 NDC 73554-2111-01)
- Tecartus (brexucabtagene autoleucel) (HCPCS code Q2053)
- Yescarta (axicabtagene ciloleucel) (HCPCS code Q2041)
- Zolgensma (onasemnogene abeparvovec-xioi) (HCPCS code J3399)
- Zynteglo (betibeglogene autotemcel) (HCPCD code J3490/J3590 NDC – 73554-3111-01)

Accordingly, claims for these drugs should **not** be submitted with modifier UD.

Note: This policy affects only the method by which specific high-cost drugs may be purchased when provided to MassHealth ACO members, and does not impact the use of 340B drugs for other members. Each of these drugs is listed on the MassHealth Acute Hospital Carve-Out List. For additional information on billing for MassHealth Acute Hospital Carve-Out Drugs, see the section below. The Plan currently pays the actual acquisition cost for such drugs regardless of whether the drug is acquired through the 340B Drug Pricing Program or not. The Plan will continue to pay providers the actual acquisition cost for such drugs after this policy is implemented.

Sources:

MassHealth All Provider Bulletin 366 (May 2023), as updated by MassHealth All Provider Bulletin 390 (April 2024).

MassHealth Acute Hospital Carve-Out Drugs

Fallon Health requires hospitals to take the following actions with respect to drugs on the MassHealth Acute Hospital Carve-Out List for MassHealth ACO plan members:

1. Drugs and biologics on the MassHealth Acute Hospital Carve-Out Drugs List require prior authorization. The hospital must obtain prior authorization for the drug or biologic from Fallon Health or our designated pharmacy vendor – this prior authorization is separate from any prior authorization that may be required for the member’s inpatient or outpatient encounter.
2. A drug or biologic designated by MassHealth as a carve-out drug must not be included on the facility/institutional claim that the hospital submits for the plan member’s inpatient or outpatient encounter.
3. The hospital must instead submit a separate claim for the carve-out drug on a facility/institutional claim form (i.e., UB-04). (In other words, the drug is the only item on the UB-04 claim.) The charge reported on the claim must be the “hospital’s actual acquisition cost” for the drug.*
4. The claim for the carve-out drug must be reported with revenue code 0636 (Drugs requiring detailed coding), the HCPCS code for the drug, the National Drug Code (NDC) for the drug, and number of units administered.
5. The hospital must also include the following as separate attachments to the claim:
 - a. A statement of the hospital’s actual acquisition cost of the carve-out drug (as defined below) used to treat the member; and
 - b. A copy of the invoice(s) for the carve-out drug from the drug manufacturer, supplier, distributor, or other similar party or agent; and
 - c. Other additional documentation that the Plan deems necessary to evidence the hospital’s actual acquisition cost of the carve-out drug.

* For purposes of this requirement, the “hospital’s actual acquisition cost” of the carve-out drug is defined as follows:

“...the hospital’s invoice price for the drug, net of all on-or-off invoice reductions, discounts, rebates, charge backs and similar adjustments that the hospital has or will receive from the drug manufacturer or other party for the drug that was administered to the member including any efficacy, outcome, or performance-based guarantees (or similar arrangements), whether received pre-or post-payment.”

The MassHealth Acute Hospital Carve-out Drugs List is available at:

<https://masshealthdruglist.ehs.state.ma.us/MHDL/>. This list may be updated from time to time.

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, 9999999.999)
- 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.

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.

Excluded products

This policy does not apply to Fallon Health Weinberg MLTC as drugs and biologicals are not covered services under this plan.

Policy history

Origination date:	11/1/2009
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 exclusions 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.
April 2024 – Under Billing/coding guidelines, added new section for Drugs Designated for Exclusion from 340B Coverage.

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.