Drugs and Biologicals Payment Policy

Policy

The Plan reimburses contracted providers for the provision of covered, FDA-approved, non-self-administered drugs when given in an outpatient setting. This policy also applies to drugs administered by a provider via an implantable (biochemical materials or devices intended by the physician to remain in the body for at least 30 days) drug delivery system and to brachytherapy sources.

The Plan anticipates that providers will administer drugs to members in such a way that they can use the drugs most efficiently, in a clinically appropriate manner. 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.

When drugs are eligible for separate reimbursement, Plan reimbursement is for pharmaceuticals which are administered to a Plan member, only up to the next incremental Level II HCPCS code unit.

Reimbursement

The Plan anticipates that providers will administer drugs to members in such a way that they can use the drugs most efficiently, in a clinically appropriate manner. The Plan reimburses the provision of covered, FDA-approved, non-self-administered drugs when given in an outpatient setting. Plan reimbursement is for pharmaceuticals 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. The Plan anticipates that the provider 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 outlined in the Billing/Coding section of this policy.

Reimbursement will be made in accordance with contracted rates. Effective December 1, 2018 this policy will be applicable to in-patient facilities excluding payments made as part of a Diagnosis Related Group (DRG) methodology.

Referral/notification/prior authorization requirements

The facility or ordering physician is required to obtain prior authorization for drugs that are on the list of formulary medications that require prior authorization (this list can be found in the Provider Pharmacy section of the Plan’s website).

Pharmacy Prior Authorization Forms must be completed and faxed to 1-508-791-5101. For urgent situations, please call 1-866-275-3247 and select option 5.

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**

Bill pharmaceuticals with both the NDC number and the appropriate Level II HCPCS codes; bill with a count when indicated. Claims submitted with Revenue Code 0636 must include the HCPCS code.

**Fallon Health requires NDC, quantity and unit of measure for all unspecified codes for Commercial, Medicare and Medicaid including:** A9699, J3490, J3590, J7599, J7699, J7799, J7999, J8498, J8499, J8597, J8999, J9999 and C9399

**MassHealth** requires NDC information on all Single-Source Drugs as defined by CMS, with the exceptions listed below:

1. Inpatient Claims
2. Outpatient claims that are part of a bundled rate or global fee
3. Radiopharmaceuticals
4. Contrast media
5. Vaccines
6. Devices

With the exception of the scenarios listed above, claims for services for Plan members enrolled through MassHealth that are submitted without NDC information will be denied. In order to be paid, a claim adjustment request with the NDC information will need to be submitted to the Pan.

MassHealth will supply a list of HCPCS that require NDC codes to the Plan. This list is exhibit A of this policy. This list will be updated at least annually.

Effective **July 1, 2019 for all claims with dates of service beginning May 1, 2019** and forward, all NaviCare® and MassHealth Accountable Care Organization (ACO) contracted physicians and facilities will be required to submit **appropriate units of measure on all physician-administered drug claims for NaviCare HMO SNP, NaviCare SCO and MassHealth ACO enrollees.**

These codes are required per MassHealth to assist with the electronic data exchange. Claims submitted without applicable units of measure will be subject to review after July 1, 2019.

Effective **September 1, 2019, applicable claims submitted without the unit of measure codes will be denied in accordance with MassHealth regulations.** Providers who receive these denials will have the opportunity to correct and resubmit these claims following the standard protocols outlined in the Fallon Health Provider Manual.

**See below for a list of appropriate units:**

<table>
<thead>
<tr>
<th>#</th>
<th>Unit</th>
<th>Description</th>
<th>MassHealth Pharmacy Online Processing System (POPS) suggested rules</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>F2</td>
<td>International unit (for example, anti-hemophilia factor)</td>
<td>Physician-administered drug claims only</td>
</tr>
<tr>
<td>2</td>
<td>GR</td>
<td>Gram (for creams, ointments and bulk powder)</td>
<td>Physician-administered drug claims only</td>
</tr>
<tr>
<td>3</td>
<td>ME</td>
<td>Milligrams (for creams, ointments and bulk powder)</td>
<td>Physician-administered drug claims only</td>
</tr>
<tr>
<td>4</td>
<td>UN</td>
<td>Unit (for tablets, capsules, suppositories and powder-filled vials)</td>
<td>Physician-administered drug claims only</td>
</tr>
<tr>
<td>5</td>
<td>ML</td>
<td>Milliliters (for liquids, suspensions and lotions)</td>
<td>Physician-administered drug claims and pharmacy claims</td>
</tr>
</tbody>
</table>
For providers submitting electronic claims, this data is reported via the specification below from the PH-02 MassHealth Custom Interface guide – 837 Medication Claims:

| MassHealth Data Field Name                  | Attributes/Data type Length | Source Derived/MassHealth derived | Usage Required (R) or Situational (S) | MassHealth Requirement Description (MHRD)                                      |
|---------------------------------------------|------------------------------|----------------------------------|---------------------------------------|==================================================================================|
| Unit or Basis for Measurement Code          | Alpha Numeric-2              | CTP05-1                          | R                                     | Code specifying the units in which a value is being expressed, or manner in which a measurement has been taken. Values = F2 -International Unit GR -Gram ME -Milligram ML -Milliliter UN -Unit |

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. N49999999999). Report the NDC quantity in positions 17 through 24 of the same red shaded
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).

**Pharmaceutical Waste:**
- 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 pharmaceuticals which are administered to a Plan member, only up to the next incremental Level II HCPCS code unit. Wasted pharmaceutical 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 pharmaceutical, as well as the amount of wasted medication. Documentation of waste must be retained within the patient’s medical record and/or made available to Plan audit representatives upon request.
- Modifier JW (drug amount discarded/not administered to any patient): The Plan anticipates that providers will administer drugs to members in such a way that they can use the drugs most efficiently, in a clinically appropriate manner. The Plan also anticipates that 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. Effective 1/1/17, CMS requires the use of the JW modifier on Part B Drug claims for unused drugs or biologicals from single use vials/packages that are appropriately discarded, and requires that providers document the amount of discarded drugs or biologicals 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.

**Electronic claim submitters:**
Submit both the HCPCS J code and NDC number in the HIPAA-compliant format.

**Paper claim submitters:**
- CMS-1500 form: Bill both the HCPCS J code and NDC number in field 24D; place the NDC number under the Level II HCPCS code; bill units in field 24G.
- UB-04 form: Bill the Level II HCPCS code in field locator 44; the NDC number in field locator 43; service units in field locator 46.

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 pharmaceuticals that were not administered.

**Place of service**
This policy applies to services rendered in the outpatient and inpatient setting.

**Policy history**

<table>
<thead>
<tr>
<th>Origination date:</th>
<th>11/1/09</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous revision date(s):</td>
<td></td>
</tr>
<tr>
<td>07/01/2010 – updated language in the Policy, Reimbursement and Billing/coding guidelines sections to indicate policy and process regarding pharmaceutical waste.</td>
<td></td>
</tr>
<tr>
<td>01/01/2012 - Updated billing/coding guidelines to add discussion about revenue code 0636.</td>
<td></td>
</tr>
<tr>
<td>05/01/2012 - Removed requirement for itemized invoice with revenue code 0636.</td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td></td>
</tr>
<tr>
<td>02/01/2013 – Updated NDC billing requirements for members enrolled through MassHealth.</td>
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</tr>
</tbody>
</table>
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 Table B medical drug criteria as it will now be posted on the Fallon medical benefit drug lookup and updated monthly. Removed Exhibit A. NDC requirement for MassHealth will still be a requirement.

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.