Clinician-Administered Drugs Frequently Asked Questions

Medicaid and the Children with Special Health Care Needs (CSHCN) Services Program may reimburse providers only for **clinician-administered drugs** and biologicals whose manufacturers participate in the Centers for Medicare & Medicaid Services (CMS) Drug Rebate Program and that show as active on the CMS list for the date of service the drug is administered. Clinician-administered drugs that do not have a rebatable NDC will not be reimbursed by Texas Medicaid or the CSHCN Services Program. Please note there may be ingredients in a compound that are not considered a drug under the Federal Food, Drug, and Cosmetic Act.

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General

Q1. Why do I have to start billing with National Drug Codes in addition to Healthcare Common Procedure Coding System codes?

The Deficit Reduction Act of 2005 (DRA) includes new provisions regarding State collection of data for the purpose of collecting Medicaid drug rebates from drug manufacturers for clinician-administered drugs. Section 6002 of the DRA adds section 1927(a)(7) to the Social Security Act to *require* States to collect rebates on clinician-administered drugs. In order for Federal Financial Participation (FFP) to be available for payment of these drugs, the State must provide collection and submission of utilization data in order to secure rebates.

Since there are often several National Drug Codes (NDC) linked to a single Healthcare Common Procedure Coding System (HCPCS) code, the Centers for Medicare and Medicaid Services (CMS) deem that the use of NDC numbers is critical to correctly identify the drug and manufacturer in order to invoice and collect the rebates.

Q2. Can you confirm this requirement is for outpatient claims only?

Yes, this requirement applies to all drug products administered by a clinician in outpatient settings, including physician's office, clinic, hospital and any other outpatient setting. The only exceptions to the NDC requirement are institutional inpatient claims.

Q3. Do radiopharmaceuticals or contrast media require an NDC?

No. Diagnostic products such as vaccines, devices and radiopharmaceuticals are not considered "covered outpatient drugs" and are not included because the NDCs were not found in the CMS drug database.

About the National Drug Code

Q4. What is a National Drug Code?

The National Drug Code (NDC) is the number that uniquely identifies each drug. The NDC number consists of 11 digits in a 5-4-2 format:

- The first 5 digits identify the labeler code representing the manufacturer of the drug and are assigned by the Food and Drug Administration (FDA).
- The next 4 digits identify the specific drug product and are assigned by the manufacturer.
- The last 2 digits define the product package size and are also assigned by the manufacturer.

Some packages may display less than 11 digits. In those cases leading zeroes can be assumed and will be required for billing. For example:

NDC on Label	Format Configuration on Label	NDC Converted to 5-4-2 Format
05678-123-01	5-3-2	05678-**0**123-01
5678-0123-01	4-4-2	**0**5678-0123-01
05678-0123-1	5-4-1	05678-0123-**0**1

Note: NDCs listed in the above table also have hyphens between the segments for easier visualization. NDCs submitted on claims should not include hyphens or spaces between segments. Be sure to include any leading zeros to maintain the 5-4-2 configuration.

Q5. Which NDC do we use, the one from the package or the vial?

Providers should use the NDC listed on the vial that is actually dispensed. The NDC is found on the drug container (i.e. vial, bottle, or tube). The NDC submitted to Medicaid must be the actual NDC number on the package or vial from which the medication was administered. If the vial is removed from a carton of similar vials, use the NDC on the individual bottle (inner package NDC) and not the NDC from the carton (outer package NDC). The only exception to this is if the vial is part of a kit that contains multiple products. In this case use the NDC on the kit.

Do not bill for one manufacturer's product and dispense another. The benefits of accurate billing include reduced audits, telephone calls, and manufacturers' disputes of their rebate invoices. It is considered a fraudulent billing practice to bill using an NDC other than the one administered.

Q6. If a labeler is included on the list of drug manufacturers participating in the CMS Medicaid Drug Rebate Program, are all products with that labeler code covered?

Yes, all outpatient drugs manufactured by that labeler are considered rebate eligible and covered.

Q7. Do all J-code claims (or other drug codes) require an NDC, NDC Quantity, and NDC Unit of Measure?

No, not all J-code claims require the submission of an NDC, NDC Quantity, and NDC Unit of Measure. All procedure codes listed on the Texas NDC-to-HCPCS Crosswalk require an NDC. Beginning June 1, 2015, the NDC Quantity and NDC Unit of Measure will also be required.

Units of Measure

Q8. What are the differences between the HCPCS Unit of Measure to the NDC Unit of Measure?

HCPCS units are billed by the number of units actually administered. The HCPCS procedure code description identifies the unit amount to calculate the number of units to be billed.

NDC units are based upon the volume of the quantity administered to the patient and the unit of measurement. The actual metric decimal quantity and the NDC Unit of Measurement are required for billing the NDC units. If reporting a fraction, use a decimal point. The allowable NDC Unit of Measurement values are:

- UN – Unit
- ML – Milliliter
- GR – Gram
- F2 – International unit
- ME – Milligram (do not use "MG" for a milligram unit of measure).

Q9. How do I convert the HCPCS Unit of Measure to the NDC Unit of Measure?

Generally, NDC unit of measure follow the examples below:

a) If the drug is in powder form and has to be reconstituted before administration then the quantity should be submitted on the claim using the "UN" designation for each vial (unit/each) used.
b) If the drug is in a kit then the quantity should be submitted using the "UN" designation.
c) If the drug is in a liquid dosage form then the quantity should be submitted on the claim using the "ML" designation for milliliters.
d) If the drug is in the dosage form of an ointment, cream, inhaler, or a bulk powder in a jar, the unit of measure primarily used is Gram (GR).
e) If the drug dosage for is in International Units then the quantity should be submitted on the claim using the "F2" designation. Blood factor products use the International Unit to delineate the dosage of the product.

Examples:

1) A patient receives 4 mg Zofran IV in the physician's office. The NDC of the product used was 00173-0442-02 (Zofran 2 mg/ml in solution form). There are 2 milliliters per vial. The provider should bill J-2405 (ondansetron hydrochloride, per 1 mg) with 4 HCPCS units and NDC units as 2 ML because this drug comes in liquid form.
2) A patient receives 1 gm Rocephin IM in the physician's office. The NDC of the product used was 00004-1963-02 (Rocephin 500 mg vial in a powder form that is reconstituted prior to the injection). The provider should bill J-0696 (ceftriaxone sodium, per 250 mg) with 4 HCPCS units and NDC units as 2 UN because this drug comes in powder form.

The following conversion chart may assist in determining which NDC unit of measurement code is applicable for a given claim:

NDC UNIT OF MEASURE DESCRIPTION	DOSAGE ADMINISTERED TO PATIENT	NDC INFORMATION ON VIAL/BOX	NDC BILLING UNIT	HCPCS CODE DESCRIPTION	HCPCS CODE BILLING UNIT
ML= Milliliters: Any liquid form of anything (syrups, IV solutions, injectable in liquid form etc.)	4 mg	2 mg/ml	2 ml	1 mg	4
EA = Each: Any single unit (for single dosage units like capsules, tablets, kits, vials with powder that has to be reconstituted, etc.).	5 gm	500 mg	10 un	250 mg	20
GR= Grams: Powders, ointments, creams, etc.	3 gm	1 gm	3 gm	500 mg	6
F2= (International Units): International units pertaining to a product's strength and not volume	6192 IU	516 U/VL	12 IU	Per IU	6192

An additional resource is the Texas Medicaid Provider Procedure Manual.

Q10. Are the corresponding unique quantity & units of measure required along with the NDC?

Yes, claims will edit for the submitted NDC Unit of Measurement beginning June 1, 2015, for both managed care and fee-for-service Medicaid claims. The submitted Unit of Measurement should reflect the volume measurement administered in the NCPDP (pharmacy) unit of measure. Refer to the "NDC Package Measure" column on the Texas NDC-to-HCPCS Crosswalk.

Claims without the proper NDC quantity and units of measurement associated with the NDC will deny. Claims will edit for the value submitted in the NDC Unit Quantity field. In order to convert the HCPCS units submitted into the NDC Unit Quantity; use the Texas NDC-to-HCPCS Crosswalk to review the "HCPCS Description", the "NDC Label" description, and the "NDC Package Measure" columns to help calculate the NDC Unit Quantity.

Both the CMS 1500 and the UB04 CMS 1450 claim forms allow for inclusion of these fields.

Claim Processing

Q11. Do I bill the HCPCS code and NDC of a drug if I just administer the drug?

No. If the patient has a prescription filled and brings the drug into the facility to have the physician administer it, the drug may not be billed by the physician. The physician should only bill for the administration of the drug. The retail pharmacy would have already billed for the drug.

Q12. Is the NDC required for services billed to the Medicaid managed care health plans for assigned members?

Yes, Medicaid managed care claims are now included in the CMS requirement. Because of the changes in the law under section 2501(c) of the Patient Protection and Affordable Care Act (PPACA), states must collect manufacturers' rebates for drugs dispensed to individuals (including clinician-administered drugs) enrolled with a Medicaid managed care health plan, effective March 23, 2010. In order to facilitate the collection of these rebates, states must include utilization data, which includes the NDC, NDC Quantity and NDC Unit of Measure reported by each managed care health plan.

Q13. Should the entire claim reject when a single line item is missing the NDC?

The requirement for inclusion of rebate eligible NDCs apply to both fee-for-service and Medicaid managed care. Some managed care health plans may only reject the line item while others may reject the entire claim. Plans may include this as a clean claim element, as allowed by the Texas Department of Insurance, under their clean claim rules.

Only the line item will reject for Medicaid fee-for-service claims.

Medicaid managed care health plan will use the same list of procedure codes as TMHP when processing claims for clinician-administered drugs. Providers must refer to the individual managed care health plan for specific questions or details regarding the enforcement of this requirement in managed care.

Q14. Some managed care health plans are rejecting claims for vaccines when they are submitted without NDC. Can you instruct them not to reject vaccines without NDC's?

HHSC has clarified to the health plans that vaccines are exempt from this requirement. Please contact the plan directly for further issues. If you are unable to reach a resolution, you may submit an official complaint to hpm_complaints@hhsc.state.tx.us.

Q15. What do I do when I receive a denial for an invalid NDC/HCPCS combination but the provider believes the NDC should be included on the Texas Crosswalk?

Providers who believe that NDCs are missing for a specific HCPCS procedure code may send an email to **vdp_cad@hhsc.state.tx.us** to request that research be performed. The provider will need to include the procedure code in question and the corresponding NDCs that are believed to be missing from the Texas NDC-to-HCPCS Crosswalk.

Q16. Is NDC reporting required for outpatient Ambulatory Surgical Centers (ASC) billing on the UB04, which is one-line claim reporting?

At this time, ASC surgical billing claims are not required to submit informational details regarding the services that are bundled into the group rate. This requirement does not apply to ASC surgical claims. However, the NDC requirement does apply to outpatient facility claims submitted on the UB-04 inpatient claim form.

Q17. Itemization can cause a claim to contain more than 28 charge lines. How do we bill more charge lines to include all NDCs?

If claim details exceed 28 charge lines, multiple claims must be submitted with the wording "Continued" at the bottom of the claim form. Please refer to the Texas Medicaid Provider Procedures Manual for appropriate billing instructions. This is an existing rule that did not change with the implementation of NDC requirements.

Q18. Does the TMHP Portal accept NDCs?

The TMHP claims portal uses the ANSI standard X12 5010 format which accommodates 11-digit NDC submissions. If the provider cannot enter an NDC for a clinician-administered drug through the portal he or she should contact the software provider that interfaces with the portal.

Q19. Are Medicare primary claims excluded from the NDC requirement?

No, Medicare primary claims require NDCs with the HCPCS codes.

Q20. Do I bill the HCPCS code and NDC of a drug if I just administer the drug?

No. If the patient has a prescription filled and brings the drug into the facility to have the physician administer it, then the drug may not be billed by the physician. The physician should only bill for the administration of the drug. The retail pharmacy would have already billed for the drug.

Q21. How do I bill for a drug when only a partial vial was administered?

The provider must bill Medicaid only for the units administered. Medicaid does not reimburse for drug waste for single or multi-use vials.

Q22. I am a 340B participating hospital. Do I need to submit NDC codes for drug claims?

Yes. While 340B purchased claims are not eligible for drug rebates, NDCs are required to receive federal funding for the payment of the claim.

Q23. Is the NDC required for services billed to the Medicaid managed care health plans?

Yes, managed care health plans are now included in the CMS requirements. Because of the changes in the law under section 2501(c) of the Patient Protection and Affordable Care Act (PPACA), states must collect manufacturers' rebates for drugs dispensed to individuals (including clinician-administered drugs) enrolled in Medicaid managed care, effective March 23, 2010. In order to facilitate the collection of these rebates states must include utilization data, which includes the NDC, reported by each health plan.

Q24. How do I bill for compounded prescriptions?

When billing for a HCPCS code where the drug being administered has been compounded using multiple NDCs, report the procedure code once along with the primary rebate eligible NDC code. Providers must document all ingredients used for compounds in corresponding medical records.

Example:

42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48 NON-COVERED CHARGES	49
250	N458468012201ML10	J1270	010508	20	311 80		

When reporting compound drugs with more than one corresponding procedure code, report each procedure code, corresponding rebate eligible NDCs, and quantity administered on separate lines. Example:

	42 REV. CD.	43 DESCRIPTION	44 HCPCS / RATE / HIPPS CODE	45 SERV. DATE	46 SERV. UNITS	47 TOTAL CHARGES	48
1	250	N400597001625GR0.025	J2562	032514	100	200 75	
2	250	N450458030006ML20	J7040	032614	20	385 00	
3							
4							