

To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.

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**NC Medicaid
Physician's Drug Program**

**Medicaid and Health Choice
Clinical Coverage Policy No: 1B
Amended Date: March 15, 2019**

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Related Clinical Coverage Policies

Refer to <https://medicaid.ncdhhs.gov/> for the related coverage policies listed below:

1D-4, Core Services Provided in Federally Qualified Health Centers and Rural Health Clinics
9, Outpatient Pharmacy Program,

1.0 Description of the Procedure, Product, or Service

The Physicians Drug Program (PDP) covers many, but not all, primarily injectable drugs that are purchased and administered in a physician's office or in an outpatient clinic setting.

1.1 Definitions

Throughout this policy, the use of the term "physician" may refer to other appropriate providers. The terms "drug" or "medication" may refer to a drug or biologic agent. The term "injectable drug" may refer to a drug that can be infused.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

(The term "General" found throughout this policy applies to all Medicaid and NCHC policies)

- a. An eligible beneficiary shall be enrolled in either:
 1. the NC Medicaid Program (*Medicaid is NC Medicaid program, unless context clearly indicates otherwise*); or
 2. the NC Health Choice (*NCHC is NC Health Choice program, unless context clearly indicates otherwise*) Program on the date of service and shall meet the criteria in **Section 3.0 of this policy**.
- b. Provider(s) shall verify each Medicaid or NCHC beneficiary's eligibility each time a service is rendered.
- c. The Medicaid beneficiary may have service restrictions due to their eligibility category that would make them ineligible for this service.
- d. Following is only one of the eligibility and other requirements for participation in the NCHC Program under GS 108A-70.21(a): Children must be between the ages of 6 through 18.

2.1.2 Specific

(The term "Specific" found throughout this policy only applies to this policy)

- a. **Medicaid**
None Apply.
- b. **NCHC**
None Apply.

2.2 Special Provisions

2.2.1 EPSDT Special Provision: Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age

a. 42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]

Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiary under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed practitioner).

This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his or her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

Medically necessary services will be provided in the most economic mode, as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product or procedure:

1. that is unsafe, ineffective, or experimental or investigational.
2. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and other specific criteria described in clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

b. EPSDT and Prior Approval Requirements

1. If the service, product, or procedure requires prior approval, the fact that the beneficiary is under 21 years of age does **NOT** eliminate the requirement for prior approval.
2. **IMPORTANT ADDITIONAL INFORMATION** about EPSDT and prior approval is found in the *NCTracks Provider Claims and Billing Assistance Guide*, and on the EPSDT provider page. The Web addresses are specified below.

NCTracks Provider Claims and Billing Assistance Guide:
<https://www.nctracks.nc.gov/content/public/providers/provider-manuals.html>

EPSDT provider page: <https://medicaid.ncdhhs.gov/>

2.2.2 EPSDT does not apply to NCHC beneficiaries

2.2.3 Health Choice Special Provision for a Health Choice Beneficiary age 6 through 18 years of age

NC Medicaid shall deny the claim for coverage for an NCHC beneficiary who does not meet the criteria within **Section 3.0** of this policy. Only services included under the NCHC State Plan and the NC Medicaid clinical coverage policies, service definitions, or billing codes are covered for an NCHC beneficiary.

3.0 When the Procedure, Product, or Service Is Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

3.1 General Criteria Covered

Medicaid and NCHC shall cover the procedure, product, or service related to this policy when medically necessary, and:

- a. the procedure, product, or service is individualized, specific, and consistent with symptoms or confirmed diagnosis of the illness or injury under treatment, and not in excess of the beneficiary's needs;
- b. the procedure, product, or service can be safely furnished, and no equally effective and more conservative or less costly treatment is available statewide; and
- c. the procedure, product, or service is furnished in a manner not primarily intended for the convenience of the beneficiary, the beneficiary's caretaker, or the provider.

3.2 Specific Criteria Covered

3.2.1 Specific criteria covered by both Medicaid and NCHC

The PDP covers drugs, primarily injectable, for use in an office or outpatient clinic setting. Drugs covered in the PDP include therapeutic drugs, some implants, biologic agents, immune globulins, vaccines, and therapeutic radiopharmaceutical agents.

Injectable medications are covered only when oral medications are contraindicated.

In the PDP, indications approved by the Food and Drug Administration (FDA) are generally covered. In addition, off-label uses of an approved drug may be covered if the data on the drug's use are consistent with the compendia and peer-reviewed medical literature, according to 42 U.S.C. 1396r-8(g)(1)(B), or as determined by NC Medicaid.

Specific drug policies can be found in Section 1B of the Medicaid clinical coverage policies list at <https://medicaid.ncdhhs.gov/>. Providers are also encouraged to refer to the Medicaid Bulletin, published monthly, that contains individual articles regarding drugs, including billing guidelines such as diagnosis code requirements.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

3.2.3 NCHC Additional Criteria Covered

None Apply.

4.0 When the Procedure, Product, or Service Is Not Covered

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

4.1 General Criteria Not Covered

Medicaid and NCHC shall not cover the procedure, product, or service related to this policy when:

- a. the beneficiary does not meet the eligibility requirements listed in **Section 2.0**;
- b. the beneficiary does not meet the criteria listed in **Section 3.0**;
- c. the procedure, product, or service duplicates another provider's procedure, product, or service; or
- d. the procedure, product, or service is experimental, investigational, or part of a clinical trial.

4.2 Specific Criteria Not Covered

4.2.1 Specific Criteria Not Covered by both Medicaid and NCHC

None Apply.

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

4.2.3 NCHC Additional Criteria Not Covered

- a. NCGS § 108A-70.21(b) "Except as otherwise provided for eligibility, fees, deductibles, copayments, and other cost sharing charges, health benefits coverage provided to children eligible under the Program shall be equivalent to coverage provided for dependents under North Carolina Medicaid Program except for the following:
 1. No services for long-term care.
 2. No nonemergency medical transportation.
 3. No EPSDT.
 4. Dental services shall be provided on a restricted basis in accordance with criteria adopted by the Department to implement this subsection."

5.0 Requirements for and Limitations on Coverage

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

5.1 Prior Approval

Medicaid and NCHC shall not require prior approval for Physician's Drug Program.

5.2 Prior Approval Requirements

5.2.1 General

None Apply.

5.2.2 Specific

None Apply.

5.3 Limitations or Requirements

5.3.1 Expense to the Provider

The costs of drugs or biologic agents billed for Medicaid and NCHC beneficiaries by the provider through the PDP program must represent an expense actually incurred by the provider. For example, if a drug has been provided by a drug manufacturer at no cost to the provider, that drug must not be billed to Medicaid or NCHC.

5.3.2 Program Restrictions and Limitations

Not all injectable drugs are **automatically** covered in the PDP. Similarly, an injectable drug covered by Medicare is **not necessarily** covered in the PDP.

Some injectable drugs and biologicals are covered through the Outpatient Pharmacy Program, some are covered through the PDP, and some are covered in both programs. Those drugs reimbursable through the PDP may be found on the PDP fee schedule at: <https://medicaid.ncdhhs.gov/>. Providers may also call CSC at 1-800-688-6696 with the HCPCS code for the drug, to obtain information regarding coverage of the drug. The caller shall indicate which program they are referencing (PDP vs. Outpatient Pharmacy).

Drugs covered through the PDP must be subject to a manufacturer's rebate agreement on file with the Centers for Medicare and Medicaid Services (CMS). The list of participating manufacturers is updated quarterly and is announced in the Pharmacy Newsletters.

5.3.3 Drug Restrictions and Limitations

There may be restrictions regarding the age and gender of the beneficiaries who may receive a particular drug. Some drugs may have specific billing requirements or unit limitations; e.g., specific diagnosis codes or number of units allowed per time frame. Providers may call CSC at 1-800-688-6696 regarding coverage of a specific ICD-9-CM diagnosis code or limitations for a specific drug. Refer also to drug-specific general bulletin articles for more information.

Providers who determine that the indications or dosing for a particular drug is medically necessary for a beneficiary, but those parameters fall outside of the guidelines for that drug, may submit medical record information to the NC Medicaid Assistant Director for Clinical Policy for a case-by-case review. The address to send this information is:

Assistant Director for Clinical Policy and Programs
Division of Health Benefits
NC Medicaid
2501 Mail Service Center
Raleigh, NC 27699-2501

5.3.4 Outpatient Pharmacy Point-of-Sale Medications

Medicaid and NCHC also cover outpatient drugs through the Outpatient Pharmacy Program. These programs cover prescription drugs that are approved by the FDA and are included in a manufacturer's rebate agreement on file with CMS. Drugs that meet these criteria are automatically covered through the Outpatient Pharmacy Program, unless NC Medicaid determines that the drug will be covered only for use in an office setting and not by prescription. In this case, the drug will be covered only through the PDP.

Note: FDA-approved and rebatable drugs that **are not** covered through the PDP may be covered through the Outpatient Pharmacy Program. Drugs covered through the Outpatient Pharmacy Program must be obtained by prescription. (Pharmacies bill Medicaid and NCHC for all drugs through an online point-of-sale system.) Refer to clinical coverage policy 9, *Outpatient Pharmacy Program*, at <https://medicaid.ncdhhs.gov/>.

5.3.5 340-B Federal Drug Pricing Program

The PDP reimburses for drugs billed to Medicaid and NCHC by 340-B participating providers who have registered with the Office of Pharmacy Affairs (OPA) at <http://opanet.hrsa.gov/opa/CE/CEMedicaidextract.aspx>. The 340-B federal pricing program provides access to reduced-price prescription drugs.

6.0 Providers Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for procedures, products, and services related to this policy, providers shall

- a. meet Medicaid or NCHC qualifications for participation;
- b. be currently Medicaid - enrolled; and
- c. bill only for procedures, products, and services that are within the scope of their clinical practice, as defined by the appropriate licensing entity.

6.1 Provider Qualifications and Occupational Licensing Entity Regulations

Physicians and qualified practitioners, podiatrists, health departments, and health department family planning clinics enrolled in Medicaid who provide these services may bill for these services. In all instances, however, it may not be appropriate for providers to bill certain drugs. Refer to **Attachment A** for billing guidelines. Federally Qualified Health Centers (FQHCs) and Rural Health Clinics (RHCs) should refer to clinical

coverage policy 1D-4, *Core Services Provided in Federally Qualified Health Centers and Rural Health Clinics*, at <https://medicaid.ncdhhs.gov/>.

7.0 Additional Requirements

Note: Refer to Subsection 2.2.1 regarding EPSDT Exception to Policy Limitations for a Medicaid Beneficiary under 21 Years of Age.

7.1 Compliance

Provider(s) shall comply with the following in effect at the time the service is rendered:

- a. All applicable agreements, federal, state and local laws and regulations including the Health Insurance Portability and Accountability Act (HIPAA) and record retention requirements; and
- b. All NC Medicaid's clinical (medical) coverage policies, guidelines, policies, provider manuals, implementation updates, and bulletins published by the Centers for Medicare and Medicaid Services (CMS), DHHS, DHHS division(s) or fiscal contractor(s).

8.0 Policy Implementation/Revision Information

Original Effective Date: January 1, 1973

Revision Information:

Date	Section Revised	Change
03/12/2012	All sections and attachment(s)	Initial promulgation of current coverage. Technical changes to merge Medicaid and NCHC current coverage into one policy.
07/01/2013	Attachment A	H.6 Drugs Billed With Invoice – Added clarifying language
07/01/2013	All sections and attachment(s)	Replaced “recipient” with “beneficiary.”
07/01/2013	Subsections 5.3.2 and 5.3.3	Changed “HP Provider Services” to “CSC.”
10/01/2015	All Sections and Attachments	Updated policy template language and added ICD-10 codes to comply with federally mandated 10/1/2015 implementation where applicable.
05/15/2018	Attachment A, Section H.7.	Updated language to include vaccines to all claims that require NDCs.
03/15/2019	Table of Contents	Added, “To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after November 1, 2019, please contact your PHP.”
03/15/2019	All Sections and Attachments	Updated policy template language.

Attachment A: Claims-Related Information

Provider(s) shall comply with the, *NCTracks Provider Claims and Billing Assistance Guide*, Medicaid bulletins, fee schedules, NC Medicaid's clinical coverage policies and any other relevant documents for specific coverage and reimbursement for Medicaid and NCHC:

A. Claim Type

Professional (CMS-1500/837P transaction)

Institutional (UB-04/837I transaction)

B. International Classification of Diseases and Related Health Problems, Tenth Revisions, Clinical Modification (ICD-10-CM) and Procedural Coding System (PCS)

Provider(s) shall report the ICD-10-CM and Procedural Coding System (PCS) to the highest level of specificity that supports medical necessity. Provider(s) shall use the current ICD-10 edition and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for code description, as it is no longer documented in the policy.

Note: For beneficiaries 21 years of age and under, refer to the Health Check Billing Guide on at: <https://medicaid.ncdhhs.gov/> for billing guidelines regarding immunizations.

C. Code(s)

Provider(s) shall report the most specific billing code that accurately and completely describes the procedure, product or service provided. Provider(s) shall use the Current Procedural Terminology (CPT), Health Care Procedure Coding System (HCPCS), and UB-04 Data Specifications Manual (for a complete listing of valid revenue codes) and any subsequent editions in effect at the time of service. Provider(s) shall refer to the applicable edition for the code description, as it is no longer documented in the policy.

If no such specific CPT or HCPCS code exists, then the provider(s) shall report the procedure, product or service using the appropriate unlisted procedure or service code.

Reimbursement requires compliance with all Medicaid or NCHC guidelines, including obtaining appropriate referrals for beneficiaries enrolled in the Medicaid and NCHC managed care programs.

Unlisted Procedure or Service

CPT: The provider(s) shall refer to and comply with the Instructions for Use of the CPT Codebook, Unlisted Procedure or Service, and Special Report as documented in the current CPT in effect at the time of service.

HCPCS: The provider(s) shall refer to and comply with the Instructions For Use of HCPCS National Level II codes, Unlisted Procedure or Service and Special Report as documented in the current HCPCS edition in effect at the time of service.

D. Modifiers

Provider(s) shall follow applicable modifier guidelines.

E. Billing Units

Provider(s) shall report the appropriate code(s) used which determines the billing unit(s).
Refer to the definition of the HCPCS code and bill appropriate NDC units when billing for a drug.

F. Place of Service

Office.

G. Co-payments

For Medicaid refer to Medicaid State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

For NCHC refer to NCHC State Plan:

<https://medicaid.ncdhhs.gov/get-involved/nc-health-choice-state-plan>

H. Reimbursement

Provider(s) shall bill their usual and customary charges.

For a schedule of rates, refer to: <https://medicaid.ncdhhs.gov/>

H.1 Non-340-B Drugs

Providers shall bill their usual and customary charges.

H.2 340-B Drugs

The PDP reimburses for drugs billed for Medicaid and NCHC beneficiaries by 340-B participating providers who have registered with the OPA at <http://opanet.hrsa.gov/opa/CE/CEMedicaidextract.aspx>. Providers billing for 340-B drugs shall bill the cost that is reflective of their acquisition cost. Providers shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the "UD" modifier on the drug detail.

H.3 Administration Fees

For adults 21 years of age and older:

Medicaid usually allows an administration code to be billed with an injectable medication. However, when an injection/infusion is provided on the same day as an evaluation and management (E&M) or other service on the physician fee schedule, and the E&M code or other fee schedule service code is billed, only the HCPCS code and NDC for the *drug* may be billed. The *administration* of the injection/infusion is bundled into the reimbursement for the E&M or other physician fee schedule service provided.

If no E&M service or other service on the physician fee schedule is furnished during the visit, the appropriate administration fee (CPT codes 90471 through 90474 and 96365 through 96379) and drug codes may be billed.

If the beneficiary is seen for a separately identifiable E&M service on the same day on which an injectable drug or immunization administration code is billed, the E&M code may be billed in addition to the injectable drug or immunization administration code by appending modifier 25 to the E&M code.

For beneficiaries under 21 years of age:

Medicaid and NCHC may reimburse for an immunization administration code (e.g., CPT codes 90471EP through 90474EP for Medicaid and 90471-90474 for NCHC) in addition to an E&M code on the same day by the same provider. Refer to the Special Bulletin Health Check July 2011 at <https://medicaid.ncdhhs.gov/> for details.

When an injection or infusion is provided on the same day as an E&M code and the E&M code is billed, only the HCPCS code and NDC for the *drug* may be billed. If the beneficiary is seen for a significant, separately identifiable E&M service on the same day by the same physician on which an injectable drug administration code is billed (e.g., 96372), the E&M code may be billed in addition to the administration code by appending modifier 25 to the E&M code.

H.4 Supplies

Routine supplies necessary to administer intravenous push injections, intravenous bolus injections or infusions, intramuscular injections, or subcutaneous injections or infusions are included in the reimbursement for the administration and are not separately reimbursed.

H.5 Unclassified Drugs

Medicaid and NCHC cover some FDA-approved drugs that do not have an assigned HCPCS code. Providers shall bill unlisted or miscellaneous HCPCS codes such as J3490 (Unclassified drugs), J3590 (Unclassified biologics), or J9999 (NOC, antineoplastic drug), with the NDC assigned to the drug.

H.6 Drugs Billed With Invoice

Occasionally, a drug will be required to be billed with an invoice, such as drugs that are components of compounds. The North Carolina Pharmacy Act defines compounding as taking two or more ingredients and combining them into a dosage form of a drug, exclusive of compounding by a drug manufacturer, distributor, or packer (Chapter 90: MEDICINE AND ALLIED OCCUPATIONS – Article 4A – North Carolina Pharmacy Act; 90-85.3). Therefore, for N.C. Medicaid and NCHC Programs, any drug defined as a compound must be billed as an entity. Individual components of the compound must not be separately billed with an individual HCPCS code. The entire compound as an entity SHALL be billed under HCPCS code J3490 (miscellaneous drugs) with an invoice. The invoice must be the original invoice and must be submitted with the claim. When billing for compounds, the invoice must be the one from the compounding pharmacy.

The invoice must indicate the name of the beneficiary, the beneficiary's Medicaid identification number, the name of the medication, the dosage given, the National Drug Code (NDC), and the cost per dose. The claim must indicate the HCPCS units (usually 1 unit of J3490 when a compound is billed) and the appropriate NDC units billed.

H.7 National Drug Codes

Effective with date of service December 28, 2007, providers shall bill all applicable drug products, including vaccines, with NDCs to comply with the Deficit Reduction Act of 2005. Refer to *National Drug Code Implementation, Phase III* (March 2009 Special Bulletin), at <https://medicaid.ncdhhs.gov/> for specific billing guidelines related to NDC codes.

The Automated Voice Response (AVR) System is the most up-to-date method for checking the status of an NDC. Providers are able to verify an NDC as covered or non-covered using the AVR System (1-800-723-4337, option 3). The required information is a valid provider number, the NDC in an 11-digit format, and the date of service. For detailed instructions on the AVR System, refer to the July 2001 Special Bulletin, *Automated Voice Response (AVR) System Provider Inquiry Instructions*, at <https://medicaid.ncdhhs.gov/>.

H.8 Billing for Single-Dose or Multi-Dose Vials

Providers may bill for the entire vial when single-dose vials are used. When multi-dose vials are used, providers shall bill for only the amount actually administered.

H.9 Billing for Partially Administered Doses

Providers may bill for the entire dose of medication that was to be administered if only a partial dose was administered. For example, if the beneficiary had a reaction to the drug after only part of the dose was administered, the entire dose may be billed. Modifier 53 (discontinued procedure) may be appended to the administration code. Providers shall not bill for drugs that are prepared and not at least partially administered.

H.10 Revenue Codes

Providers shall bill applicable revenue codes.

H.11 Fee Schedules

For a schedule of rates, see: <https://medicaid.ncdhhs.gov/>.