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

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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 Administered Drug Program (PDP)(PADP)covers many, but not all, primarily most injectable drugs that are purchased and administered by a medical professional 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, and "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.

2.0 Eligibility Requirements

2.1 Provisions

2.1.1 General

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

a. An eligible beneficiary shall be enrolled in the NC Medicaid Program *(Medicaid is NC Medicaid program, unless context clearly indicates otherwise*);
b. Provider(s) shall verify each Medicaid 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.

2.1.2 Specific

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

a. Medicaid
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

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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/

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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 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 not 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 Medicaid

Medicaid shall cover ~~Physicians Administered Drug Program~~ (~~PDP~~) (PADP), drugs which are primarily injectable products (infusions, IM, SQ, etc.) for use in an office or outpatient clinic setting.

Covered drugs ~~in the PDP~~ (located in the Catalog) include therapeutic drugs, some implants, biologic agents, immune globulins, vaccines, and therapeutic radiopharmaceutical agents~~. most of which~~ Some of the drugs are eligible for rebate through the Medicaid Drug Rebate Program. Injectable medications are covered only when oral medications are contraindicated.

The prescribed drug must be approved by the Federal Drug Administration (FDA). If the prescribed drug is not FDA approved then a separate approval must be obtained by DHB, or the managed care entity for individuals under managed care, and the prescribed drug must be used for a medically accepted indication.

~~Indications approved by the Food and Drug Administration (FDA) are generally covered.in the PDP~~

Providers are encouraged to refer to the PADP ~~Physicians Drug Program Drug~~ Catalog~~ue~~ and the Medicaid Bulletins, ~~published monthly,~~ that contains individual articles regarding drugs, coverable indications, and specific billing guidelines.

3.2.2 Medicaid Additional Criteria Covered

None Apply.

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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 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 Medicaid

Medicaid shall not cover any drug, manufactured by a company that has not signed a rebate agreement. Exceptions are made for CroFab, selected vaccines, and radiopharmaceuticals. **Note:** Some radiopharmaceuticals are subject to rebates

Medicaid may restrict coverage of an outpatient drug as found in Section 1927(d)(1)(B)(i) of the Social Security Act if the prescribed drug is not for a medically accepted indication. Except the use of a covered outpatient drug, which is approved under the Federal Food, Drug, and Cosmetic Act for the prescribed use, Medicaid may cover prescribed drugs if the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).The compendia include:

a. American Hospital Formulary Service Drug Information
b. United States Pharmacopeia;
c. DRUGDEX Information System; or
d. As per 1927(d)(1)(B)(ii), peer-reviewed medical literature.

~~Providers who determine the indications for a particular drug are medically necessary, but those parameters fall outside of the predetermined standards for that drug, may submit compendia or peer-reviewed medical literature supporting its use (as per 42U.S.C. 1396r-8(g)(1)(B)) to the NC Medicaid Pharmacy Manager for review. The citations will be reviewed, and if deemed medically acceptable as defined above, will be added to the PADP Drug Catalogue.~~

When a provider determines the indication or dosing for a particular drug is medically necessary for a beneficiary, but the parameters fall outside of the FDA approved guidelines or NC Medicaid Drug Criteria for that drug, the provider may make a request for the medically necessary indication or dosing for a particular drug.

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For a beneficiary under Managed Care, please contact your Managed Care Organization for procedures to request exceptions to the FDA clinical indications.

To request approval, a provider shall submit, with the drug request forms, the following required additional information:

a. Health record information to indicate medical necessity for the requested drug;
b. An explanation of what other drugs have been utilized or why they cannot be used;
c. An explanation from the prescribing medical professional of why the FDA approved guidelines and evidence-based standards for that drug or NC Medicaid Drug Criteria is insufficient for this beneficiary and
d. Compendia or Peer reviewed medical literature supporting the use of the requested drug (as per 42U.S.C. 1396r 8(g)(1)(B)).

~~For individuals under Medicaid Direct, the address to send this information is:~~

~~Pharmacy Manager for Clinical Policy and Programs Division of Health Benefits~~
~~NC Medicaid~~
~~1915 Health Services Way~~
~~1950 Mail Service Center~~
~~Raleigh, NC 27607~~

~~Providers who determine that the indications or dosing for a particular drug is medically necessary for a~~an individual ~~beneficiary, but those parameters fall outside of the predetermined standards for that drug, may submit health record information and compendia or peer reviewed medical literature supporting its use (as per 42U.S.C. 1396r 8(g)(1)(B)) to the NC Medicaid Pharmacy Manager for a case-by-case review.~~

~~The address to send this information is:~~

~~Pharmacy Manager for Clinical Policy and Programs~~
~~Division of Health Benefits~~
~~NC Medicaid~~
~~2501 Mail Service Center~~
~~Raleigh, NC 27699-2501~~

4.2.2 Medicaid Additional Criteria Not Covered

None Apply.

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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

North Carolina Medicaid Direct shall not require prior approval for the Physician's Administered Drug Program (PADP).

North Carolina Medicaid Managed Care shall have the option to establish prior authorization for selected prescription drugs in the PADP. The provider shall obtain prior approval before rendering these selected prescription drugs. Providers must refer to **Attachment B** and the beneficiary's individual health plan for guidelines required for requesting prior authorization.

Note: Clinical coverage for North Carolina Medicaid Managed Care Plans, shall be based on FDA indications, FDA approved dosages, and medically acceptable indications, and may involve prior approval. This guidance applies to new and existing products for which Medicaid has not yet developed clinical coverage criteria or determined criteria is not needed.

5.2 Prior Approval Requirements

5.2.1 General

The provider(s) shall submit to the Department of Health and Human Services (DHHS) Utilization Review Contractor the following:

a. the prior approval request; and
b. all health records and any other records that support the beneficiary has met the specific criteria in **Subsection 3.2** of this policy.

5.2.2 Specific

The provider(s) shall submit to the beneficiary's Medicaid Managed Care Health Plan the following:

a. the prior approval request; and
b. any health records needed to support the coverage request.

~~None Apply.~~

5.3 Limitations or Requirements

5.3.1 Expense to the Provider

The cost of drugs or biologic agents billed for a Medicaid beneficiary by the provider through the PADP must be submitted on a CMS-1500/837P transaction and represent an expense actually incurred by the provider. If a drug has been provided by a drug manufacturer at no cost to the provider, the drug must not be billed to Medicaid.

~~The costs of drugs or biologic agents billed for Medicaid beneficiaries by the provider through the PDP program must represent an expense actually incurred~~

by the provider. If a drug has been provided by a drug manufacturer at no cost to the provider, that drug must not be billed to Medicaid.

5.3.2 Program Restrictions and Limitations

Reimbursement in the PADP is allowed only if the drug qualifies for rebate in accordance with 42USC 1396r-8 unless otherwise noted in this policy. For example, 340B drugs will be reimbursed even though they are not eligible for rebates.

Not all injectable drugs are automatically covered. Some injectable drugs and biologicals are covered through the Outpatient Pharmacy Program (point of sale pharmacy), rather than the PADP setting, and some are covered in both programs. Drugs reimbursable through the PADP may be found on the PADP fee schedule and PADP Drug Catalogue at:

https://ncdhhs.servicenowservices.com/fee_schedules (Fee Schedule)

https://medicaid.ncdhhs.gov/physician-administered-drug-program-catalog (Catalog)

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 and Physician Drug Program Drug Catalogue at: https://medicaid.ncdhhs.gov/. Providers may also call NCTracks helpdesk 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).

5.3.3 Drug Restrictions and Limitations

Drugs may have restrictions regarding the age and gender of the beneficiary in the PADP setting.

Some drugs may have specific billing requirements or unit limitations. Medically Unlikely Edits (MUE's), as defined by the Centers for Medicare and Medicaid Services (CMS)-are applicable in the PADP setting.

Providers may call NCTracks helpdesk at 1-800-688-6696 regarding coverage of a specific ICD-10-CM diagnosis code, HCPCS code, ~~or~~ limitations for a specific drug , and perform a code search in the NCTracks provider portal for drug coverage.

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Refer to drug-specific general bulletin articles and the PADP Catalog for more information. Providers shall regularly check the Drug Catalogue for updates. PADP Catalogue for the most recent updates.

5.3.4 Outpatient Pharmacy Point-of-Sale Medications

Medicaid shall 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 is covered only for use in an office setting and not by prescription. In this case, the drug is covered only through the PDP the PADP per the Medication Restriction List.

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

5.3.5 340-B Federal Drug Pricing Program

The PDP reimburses for drugs billed to Medicaid 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.

The PADP reimburses drugs billed to Medicaid by 340-B participating providers (covered entities) who have registered with the Office of Pharmacy Affairs (OPA) at: https://www.hrsa.gov/opa/registration.

The 340-B federal pricing program provides access to reduced-price prescription drugs. All covered entities must ensure that 340-B drugs purchased and billed to NC Medicaid are used for outpatients only.

The covered entity is prohibited from transferring or reselling 340-B purchased drugs to any beneficiary not a patient of the facility. The entity is responsible for implementing systems to ensure compliance and maintain documentation of these practices.

For 340-B drugs, the provider shall bill the cost that is reflective of their acquisition cost. Provider shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the "UD" modifier on the drug detail.

The state shall extract appropriate claims from rebate invoicing and collection. This will eliminate duplicate discounts as the claims are pulled from rebate collections. Providers are responsible for billing 340-B drugs with these guidelines. Providers may be responsible for any adverse financial impact to the State for erroneously billed claims.

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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 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/.https://medicaid.ncdhhs.gov/providers/program-specific-clinical-coverage-policies.

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).

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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 applicable links and policy template language
10/01/2019	Section 1.1	Added definition of compounding
10/01/2019	Subsections 3.2.1, 4.2.1 and 5.3.3	Consolidated and updated information to clarify instructions
10/01/2019	Attachment A and H.5,	Updated link that includes the website providing comprehensive information for all drugs covered in the PDP program. Technical change to include covered Miscellaneous HCPCS codes in Section H.5
12/12/2019	Table of Contents	Updated policy template language, "To all beneficiaries enrolled in a Prepaid Health Plan (PHP): for questions about benefits and services available on or after implementation, please contact your PHP."
12/12/2019	Attachment A	Added, "Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.
06/01/2022	Attachment A, A	Clarified that Institutional claims are applicable only to Institutional Dialysis claims, as per policy 1A-34

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Date	Section Revised	Change
4/15/2023	All Sections and Attachment(s)	Updated policy template language due to North Carolina Health Choice Program's move to Medicaid. Policy posted 4/15/2023 with an effective date of 4/1/2023.
00/00/0000	Header, Title,	Updated Header to Health Benefits. Updated Policy Title, "Physician Administered Drug Program".
00/00/0000	1.0, 3.2.1, 5.1, 5.3.1, 5.3.2, 5.3.3, 5.3.4, 5.3.5, H.3	Throughout the policy changed from "PAD" to "PADP" and from Physician's Drug Program to Physician Administered
00/00/0000	3.2.1	Added "The prescribed drug must be approved by the Federal Drug Administration (FDA). If the prescribed drug is not FDA approved then a separate approval must be obtained by DHB, or the managed care entity for individuals under managed care, and the prescribed drug must be used for a medically accepted indication." and "Some of the drugs are eligible for rebate through the Medicaid Drug Rebate Program."
00/00/0000	4.2.1	Added statement under Specific Criteria Not Covered by Medicaid. "Medicaid shall not cover any drug, manufactured by a company that has not signed a rebate agreement. Exceptions are made for CroFab, selected vaccines, and radiopharmaceuticals. **Note:** Some radiopharmaceuticals are subject to rebates Medicaid may restrict coverage of an outpatient drug as found in Section 1927(d)(1)(B)(i) of the Social Security Act if the prescribed drug is not for a medically accepted indication. Except the use of a covered outpatient drug, which is approved under the Federal Food, Drug, and Cosmetic Act for the prescribed use, Medicaid may cover prescribed drugs if the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).The compendia include: American Hospital Formulary Service Drug Information United States Pharmacopeia; or DRUGDEX Information System; or

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Date	Section Revised	Change
		As per 1927(d)(1)(B)(ii), peer-reviewed medical literature. When a provider determines the indication or dosing for a particular drug is medically necessary for a beneficiary, but the parameters fall outside of the FDA approved guidelines or NC Medicaid Drug Criteria for that drug, the provider may make a request for the medically necessary indication or dosing for a particular drug. For a beneficiary under Managed Care, please contact your Managed Care Organization for procedures to request exceptions to the FDA clinical indications. To request approval, a provider shall submit, with the drug request forms, the following required additional information: Health record information to indicate medical necessity for the requested drug; An explanation of what other drugs have been utilized or why they cannot be used: An explanation from the prescribing medical professional of why the FDA approved guidelines and evidence-based standards for that drug or NC Medicaid Drug Criteria is insufficient for this beneficiary and Compendia or Peer reviewed medical literature supporting the use of the requested drug (as per 42U.S.C. 1396r 8(g)(1)(B)).” Eliminated Medicaid Direct Statement because on hold.
00/00/0000	5.1	Added requirements and limitations for Prior Approval: “North Carolina Medicaid Direct shall not require prior approval for the Physician’s Administered Drug Program (PADP).”

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Date	Section Revised	Change
		"North Carolina Medicaid Managed Care shall have the option to establish prior authorization for selected prescription drugs in the PADP. The provider shall obtain prior approval before rendering these selected prescription drugs. Providers must refer to **Attachment B** and the beneficiary's individual health plan for guidelines required for requesting prior authorization." **Added: "Note:** Clinical coverage for North Carolina Medicaid Managed Care Plans, shall be based on FDA indications, FDA approved dosages, and medically acceptable indications, and may involve prior approval. This guidance applies to new and existing products for which Medicaid has not yet developed clinical coverage criteria or determined criteria is not needed."
00/00/0000	5.2.2	Added requirements to specific prior approval: "The provider(s) shall submit to the beneficiary's Medicaid Managed Care Health Plan the following: the prior approval request; and any health records needed to support the coverage request."
00/00/0000	5.3.1 5.3.2 5.3.3 5.3.4 5.3.5	Added more detail to expense to provider Added more detail to program restrictions and limitations Added more detail to drug restrictions and limitations Added more details to 340-B Federal Drug Pricing Program "The cost of drugs or biologic agents billed for a Medicaid beneficiary by the provider through the PADP must be submitted on a CMS-1500/837P transaction and represent an expense actually incurred by the provider. If a drug has been provided by a drug manufacturer at no cost

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Date	Section Revised	Change
		to the provider, the drug must not be billed to Medicaid. "Reimbursement in the PADP is allowed only if the drug qualifies for rebate in accordance with 42USC 1396r-8 unless otherwise noted in this policy. For example, 340B drugs will be reimbursed even though they are not eligible for rebates." "Not all injectable drugs are automatically covered. Some injectable drugs and biologicals are covered through the Outpatient Pharmacy Program (point of sale pharmacy), rather than the PADP setting, and some are covered in both programs. Drugs reimbursable through the PADP may be found on the PADP fee schedule and PADP Drug Catalogue at:" "https://ncdhhs.servicenowservices.com/fee_schedules (Fee Schedule)" "https://medicaid.ncdhhs.gov/physician-administered-drug-program-catalog (Catalog)" "Drugs may have restrictions regarding the age and gender of the beneficiary in the PADP setting. " "Medically Unlikely Edits (MUE's), as defined by the Centers for Medicare and Medicaid Services (CMS)-are applicable in the PADP setting." "HCPCS code… and perform a code search in the NCTracks provider portal for drug coverage." Refer "PADP Catalog~~ue~~ for the most recent updates" "the PADP per the Medication Restriction List." "The PADP reimburses drugs billed to Medicaid by 340-B participating providers (covered entities) who have registered with the Office of

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Date	Section Revised	Change
		Pharmacy Affairs (OPA) at: https://www.hrsa.gov/opa/registration." "The 340-B federal pricing program provides access to reduced-price prescription drugs. All covered entities must ensure that 340-B drugs purchased and billed to NC Medicaid are used for outpatients only. The covered entity is prohibited from transferring or reselling 340-B purchased drugs to any beneficiary not a patient of the facility. The entity is responsible for implementing systems to ensure compliance and maintain documentation of these practices. For 340-B drugs, the provider shall bill the cost that is reflective of their acquisition cost. Provider shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the "UD" modifier on the drug detail. The state shall extract appropriate claims from rebate invoicing and collection. This will eliminate duplicate discounts as the claims are pulled from rebate collections. Providers are responsible for billing 340-B drugs with these guidelines. Providers may be responsible for any adverse financial impact to the State for erroneously billed claims."
00/00/0000	6.1	Added a link: https://medicaid.ncdhhs.gov/providers/program-specific-clinical-coverage-policies.
00/00/0000	Attachment A: A, F, H, H.2, H.7, H.8, H.11	Added "(physician office) setting", "or in an outpatient clinic setting", "For PADP (physician office) settings, providers shall bill their usual and customary charges on the CMS-1500/837P transaction. If a drug has been provided by a drug manufacturer at no cost to the provider that drug must not be billed to Medicaid.", "For 340-B drugs, the provider(s) shall bill the cost that is reflective of their acquisition cost. Provider shall indicate that a drug was purchased under a 340-

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Date	Section Revised	Change
		B purchasing agreement by appending the "UD" modifier on the drug detail. The state shall extract appropriate claims from rebate invoicing and collection. This shall eliminate duplicate discounts as the claims are pulled from rebate collections. Providers are responsible for billing 340B drugs with these guidelines. Providers may be responsible for any adverse financial impact to the State for erroneously billed claims", "The NDC must be submitted when billing for covered medications. Claims submitted without the appropriate NDC will be denied. Providers are required to bill for the actual NDC that is administered. Coverage depends on the drug's NDC status on the date of service.", "Use the JW modifier to indicate waste", "For the PADP, for a schedule of rates, see https://ncdhhs.servicenowservices.com/fee_schedules."
00/00/0000	Attachment B	A. Added: "Providers shall contact the beneficiary's Medicaid Managed Care Plan to request Prior Approval when required."

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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:

A. Claim Type

Professional (physician office) setting (CMS-1500/837P transaction)

Institutional Dialysis (UB-04/837I transaction) - (as applicable per Dialysis Clinical Coverage Policy 1A-34)

Unless directed otherwise, Institutional Claims must be billed according to the National Uniform Billing Guidelines. All claims must comply with National Coding Guidelines.

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 under 21 years of age, refer to the Health Check Billing Guide 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 guidelines, including obtaining appropriate referrals for beneficiaries enrolled in the Medicaid 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.

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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 National Drug Code (NDC) unit(s) for a drug.

F. Place of Service

Office or in an outpatient clinic setting

G. Co-payments

For Medicaid refer to Medicaid State Plan:
https://medicaid.ncdhhs.gov/meetings-notices/medicaid-state-plan-public-notices

H. Reimbursement

~~Provider(s) shall bill their usual and customary charges.~~
For PADP (physician office) settings, providers shall bill their usual and customary charges on the CMS-1500/837P transaction.

If a drug has been provided by a drug manufacturer at no cost to the provider that drug must not be billed to Medicaid.

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

H.1 Non-340-B Drugs

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

H.2 340-B Drugs

The ~~PDP~~PADP reimburse~~s~~ for drugs billed for Medicaid beneficiaries by 340-B participating providers who have registered with the OPA at ~~https://340bopais.hrsa.gov/(X(1)S(qvazkimmv0ogagl0nssmki3e))/view/homeview?AspxAutoDetectCookieSupport=1~~
https://www.hrsa.gov/opa/registration

~~In the PADP, for~~ ~~For 340-B drugs, provider(s) shall bill the cost that is reflective of their acquisition cost. Provider(s) shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the "UD" modifier on the drug detail.~~

For 340-B drugs, the provider(s) shall bill the cost that is reflective of their acquisition cost. Provider shall indicate that a drug was purchased under a 340-B purchasing agreement by appending the "UD" modifier on the drug detail.

The state shall extract appropriate claims from rebate invoicing and collection. This shall eliminate duplicate discounts as the claims are pulled from rebate collections. Providers are responsible for billing 340B drugs with these guidelines. Providers may be responsible for any adverse financial impact to the State for erroneously billed claims.

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H.3 Administration Fees

For a beneficiary 21 years of age and older:

Medicaid usually allows an administration code to be billed with an injectable medication. However, when a PDPPADP drug agent 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 PDPPADP drug agent 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 for 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 a beneficiary under 21 years of age:

Medicaid may reimburse for an immunization administration code (CPT codes 90471EP through 90474EP for Medicaid) in addition to an E&M code on the same day by the same provider. Refer to the Special Bulletin Health Check July 2013. Health Check Billing Guide

When other PDPPADP drug agents are 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 shall cover some FDA-approved drugs that do not have an assigned HCPCS code. Providers shall bill unlisted or miscellaneous HCPCS codes with the NDC assigned to the drug.

H.6 Drugs Billed with Invoice

Occasionally, a drug is required to be billed with an invoice, such as drugs that are components of compounds. For N.C. Medicaid 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 must be billed under HCPCS code J3490 (for 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.

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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

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 NDC must be submitted when billing for covered medications. Claims submitted without the appropriate NDC will be denied. Providers are required to bill for the actual NDC that is administered. Coverage depends on the drug's NDC status on the date of service.

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 administered. Use the JW modifier to indicate waste, if applicable for Health plan billing.

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. 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 the PADP, forFor a schedule of rates, see: https://medicaid.ncdhhs.gov/ https://ncdhhs.servicenowservices.com/fee_schedules.

H.12 PDP Drug Information

For complete information about specific drugs covered in the PDPPADPprogram, please refer to the Medicaid Bulletins or the PDPPADP Drug Catalog.

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Attachment B: Requesting Prior Authorization for Prescription Drugs

Providers shall contact the beneficiary's Medicaid Managed Care Plan to request prior approval when required.