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1.0 Description of the Procedure, Product, or Service

Selected non-legend, over-the-counter (OTC) products may be covered as an optional benefit for a NC Medicaid (Medicaid) or NC Health Choice (NCHC) beneficiary within the pharmacy program when:

- a. The policy guidelines listed in **Subsection 1.1** are met.
- b. The therapeutic class code (GC3) for the product is listed on the OTC list. (Refer to **Attachment B, Covered Over the Counter Products.**)
- c. The product is dispensed by a pharmacist pursuant to a lawful prescription.
- d. For medications, the manufacturer must have a valid rebate agreement with the Centers for Medicare and Medicaid Services.

Covered OTC medications are subject to the same restrictions and recommendations as any legend drug. Restrictions and recommendations such as prior authorization and quantity limits may apply (**Attachment B, Covered Over-the-Counter Products**). All other policies of the outpatient pharmacy program apply.

1.1 Definitions

None Apply.

1.2 Policy Guidelines

NC Medicaid may consider coverage for specific OTC products and OTC medications not available as legend drugs that provide cost-effective treatment as well as cost-effective alternatives to legend drugs covered by Medicaid. The decision for coverage is based on the analysis of the cost savings or potential cost benefit of coverage of the OTC product and the recommendations of the North Carolina Physician Advisory Group (NCPAG), which will consider off-label indications using an evidence-based approach. The decision for coverage is also based on a consideration of the limited ability of beneficiaries to pay out-of-pocket for relatively expensive OTC products.

DHHS and NC Medicaid may change the coverage status of an OTC drug if there are urgent patient safety concerns, medication access issues or significant financial implications. Changes will be communicated to the P&T committee by email at the time of the change and will be presented at the next scheduled P & T committee meeting and subsequent Physicians' Advisory Group (PAG) meeting.

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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

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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

- a. 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.
- b. **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.

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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 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

a. Identification of Candidate OTCs

A drug that meets any of the following criteria may be considered as a candidate for OTC coverage:

1. A Medicaid-covered legend drug approved by the FDA as an OTC drug that results in a significant cost savings to Medicaid.
Example: The OTC version of Prilosec, which is identical in strength and formulation.
2. An efficacious drug is available only as OTC and not legend, and all other legend treatments are significantly more expensive without a significant increase in effectiveness.
3. Coverage for an OTC or a group of OTCs expands treatment options because they have been shown to decrease the total cost of care for certain conditions.

Example: Allergy treatments

b. Use of Pilot Studies

When the effect of adding an OTC is uncertain in terms of utilization, cost savings, etc., limited pilot studies are recommended and may be conducted within venues such as Community Care of North Carolina demonstration projects before making the OTC available statewide.

c. Monitoring OTC Inclusion

Monitoring will occur at least annually for each product on the OTC list to assess total utilization, per member per month rates, use rates, and cost effectiveness of continuing to include the OTC on the list.

d. Removal of OTCs from Coverage

Upon the advice of the North Carolina Physician Advisory Group (NCPAG), if an OTC product fails to meet criteria for continued coverage under the pharmacy benefit; NC Medicaid may remove it from

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the covered OTC list. This information will be posted to the OTC list according to MN Medicaid's clinical coverage policy guidelines.

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

If the OTC product is not covered by the Medicaid program, it will not be covered under the NCHC program.

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."

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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 Medicaid Beneficiaries under 21 Years of Age.

5.1 Prior Approval

Prior approval may be required. Prior approval requirements are available on the Medicaid and NCHC Preferred Drug List (<https://medicaid.ncdhhs.gov/>).

5.2 Additional Limitations or Requirements

None Apply.

6.0 Provider(s) Eligible to Bill for the Procedure, Product, or Service

To be eligible to bill for the procedure, product, or service related to this policy, the provider(s) shall:

- a. meet Medicaid or NCHC qualifications for participation;
- b. have a current and signed Department of Health and Human Services (DHHS) Provider Administrative Participation Agreement; 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

None Apply.

6.2 Provider Certifications

None Apply.

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: October 1, 2003

Revision Information:

Date	Section Revised	Change
09/01/04	Section 1.0	A technical correction to clarify how over the counter medications are dispensed.
5/1/07	Section 1.0	Removed packaging requirements from item d.
2/1/09 (eff. 9/16/08)	Sections 1.0 and 2.1	Added “non-legend” to description; changed National Drug Codes (NDCs) to therapeutic class codes (GC3s).
2/1/09 (eff. 9/16/08)	Attachment A	Deleted specific NDC codes and substituted therapeutic class codes.
7/1/09 (eff. 7/17/09)	Throughout	Updated terminology to “over-the-counter products” to include syringes.
7/1/09 (eff. 7/17/09)	Attachment A	Added syringes (GC3 code X2B) to list of covered products.
7/1/2010	Throughout	Policy Conversion: Implementation of Session Law 2009-451, Section 10.32 “NC HEALTH CHOICE/PROCEDURES FOR CHANGING MEDICAL POLICY.”
11/1/10 (eff. 9/15/10)	Section 1.0	Removed reference to PAL
11/1/10 (eff. 9/15/10)	Attachment A	Added antihistamine-decongestant combination products (GC3 Code Z2O) to OTC Drug Class Description Removed the sentence: “ Note: Coverage of GC3 Z2Q does not include antihistamine-decongestant combination products.”
3/1/2012	Sections 1.0, 2.2, 2.3, Attachment A	Technical changes to merge Medicaid and NCHC current coverage into one policy.
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.
10/01/2017	Attachment B	Oral contraceptive, levonorgestrel, added to Covered OTC Products Amended policy posted on this date, with an EFFECTIVE Date of 07/01/2013.

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	<u>Subsection 1.2</u>	<u>Added: “DHHS and NC Medicaid may change the coverage status of an OTC drug if there are urgent patient safety concerns, medication access issues or significant financial implications. Changes will be communicated to the P&T committee by email at the time of the change and will be presented at the next scheduled P & T committee meeting and subsequent Physicians’ Advisory Group (PAG) meeting.”</u>
	<u>Attachment B</u>	<u>Polyethylene glycol 3350 added to Covered OTC Products and update section 1.2</u>

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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 and NCHC:

A. Claim Type

D Claim, NCPDP Claim Format

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

Not Applicable.

C. Code(s)

Not Applicable.

D. Modifiers

Not Applicable.

E. Billing Units

Tablet, capsule, milliliter (ml), grams, and each.

F. Place of Service

Not Applicable.

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, see: <https://medicaid.ncdhhs.gov/>

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Attachment B: Covered Over-the-Counter Products

OTC Drug Class Description	GC3 Code	Beginning Date of Coverage	Ending Date of Coverage
Smoking deterrent agents (nicotine)	J3A	7/20/2005	
Proton pump inhibitors	D4J	10/1/2003	
Second generation antihistamines	Z2Q	11/25/2003	
Second generation antihistamines-decongestant combination products (Quantity limits apply)	Z2O	9/15/2010	
Insulins	C4G	6/25/1991	
Syringes	X2B	7/17/2009	
Test Strips	M4A	11/15/2009	
Control Solution	Y9A	11/15/2009	
Lancets	Y3A	11/15/2009	
Lancing Device	Y9A	11/15/2009	
Pen Needles	X2A	2/26/2010	
Contraceptives, Oral (levonorgestrel)	G8A	07/01/2017	
<u>Cathartics and Laxatives -limited to polyethylene glycol 3350</u>	<u>D6S</u>		