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1.0 Policy Statement

Selected over-the-counter (OTC) medications may be covered as an optional benefit within the pharmacy program when:

- The policy guidelines listed in Section 2.0 are met;
- The national drug code (NDC) for the medication is listed on the OTC list. (Refer to Attachment A on page 3 for a copy of the North Carolina Division of Medical Assistance Covered Over the Counter Medications.)
- The medication is dispensed by a pharmacist in the manufacturer's unopened container pursuant to a lawful prescription; and
- The medication's manufacturer has a valid CMS rebate agreement.

Covered OTC medications are subject to the same restrictions and recommendations as any legend drug. Restrictions and recommendations such as prior authorization, quantity limits, and inclusion in the Prescription Advantage List (PAL) are included on the OTC list (Attachment I). Specific NDCs will be designated based on attributes such as number of doses per package, range of formulations, etc. All other policies of the outpatient pharmacy program apply.

2.0 Policy Guidelines

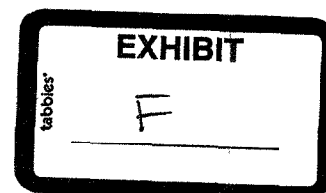
2.1 Reasons for Coverage

DMA may consider coverage for specific 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 medication 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 recipients to pay out-of-pocket for relatively expensive OTC drugs.

2.2 Identification of Candidate OTC Drugs

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

- 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.)
- An efficacious drug is available only as OTC and not legend, and all other legend treatments are significantly (i.e., >20%) more expensive without a significant increase in effectiveness
Example: Aspirin for cardiovascular disease or tinactin or lotrimin for ringworm.



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- 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.

2.3 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 the Community Care Program demonstration projects before making the OTC available statewide.

2.4 Monitoring OTC Inclusion

Monitoring will occur at least annually for each drug 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.

Quarterly monitoring shall be conducted when an OTC has a legend version to assess that the significant price differential persists.

2.5 Removal of OTC Medications from Coverage

Upon the advice of the NCPAG, if an OTC product fails to meet criteria for continued coverage under the pharmacy benefit; DMA may remove the medication from the covered OTC list. This information will be posted to the OTC list according to DMA's medical policy guidelines.

3.0 Policy Implementation/Revision Information

Effective Date: October 1, 2003

Revision Information:

| Date | Section Revised | Change |
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Attachment A

**North Carolina Division of Medical Assistance
Covered Over-the-Counter Medications**

| OTC Medication Name, Strength, and NDC Number | PA Required? | Beginning Date of Coverage | Ending Date of Coverage |
|--|---------------------|---------------------------------------|------------------------------------|
| Insulin products as per State Plan Attachment 3.1-A.1, 12A, Prescribed Drugs | No | | |
| Prilosec OTC, 20 mg 37000-0455-04 | No | 10/01/2003 | |
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OTC PRODUCTS COVERED BY NORTH
CAROLINA MEDICAID

1. All Insulin products

2. Prilosec OTC NDC: 37000-0455-04 42 count (only
Packaged size covered)

*Pharmacists should place a 34 days supply in the days supply
field to adjudicate the claim. Prescribers should write Prilosec
OTC #42---then the sig-----*

3. Clartin/Loratadine products—specific NDCs covered:

11523-7160-03 20 tablets package size Claritin OTC
*prescribers should write Claritin #40—then sig----
Pharmacists should enter 34 days in the days supply field to
adjudicate the claim*

00573-2645-30 Alavert 30 tablets package size

00113-0275-65 Loratadine 30 tablets package size

49614-0170-65 Allergy Relief 30 tablets package size

The best—cost effective product for NC Medicaid

00113-0275-65 LORATADINE 30 TABLETS

I encourage all prescribers to write for Loratadine #30 and for
pharmacists to dispense Loratadine when appropriate.