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**North Carolina  
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1-800-688-6696 or 919-851-8888

## **Prior Authorization Criteria for Botulinum Toxin Types A and B**

On November 3, 2008, the N.C. Medicaid Outpatient Pharmacy Program will add the following indications to the prior authorization (PA) criteria for coverage of botulinum toxin Type A (Botox):

- Sialorrhea
- Schilder's disease
- Quadriplegia

The following indication will be added to PA criteria for coverage of botulinum toxin Type B (Myobloc):

- Sialorrhea

Prescribers can request PA by contacting ACS at 866-246-8505 (telephone) or 866-246-8507 (fax). The updated criteria and PA request form for this medication will be available on the N.C. Medicaid Enhanced Pharmacy Program website at <http://www.ncmedicaidpbm.com>.

## **New Prior Authorization Program for Qualaquin**

On November 3, 2008, the N.C. Medicaid Outpatient Pharmacy Program will require prior authorization (PA) on the antimalarial drug Qualaquin. Coverage will be provided when the drug is used for the treatment of malaria.

Prescribers can request PA by contacting ACS at 866-246-8505 (telephone) or 866-246-8507 (fax). The criteria and PA request form for this medication will be available on the N.C. Medicaid Enhanced Pharmacy Program website at <http://www.ncmedicaidpbm.com>.

## **New Enhanced Specialty Discount on Single-Source Specialty Drugs**

Effective with the date of service October 10, 2008, the N.C. Medicaid Outpatient Pharmacy Program will utilize a State-determined upper payment limit for select single-source specialty drugs that cost in excess of \$1,500 per month. This is in compliance with a N.C. General Assembly mandate in Session Law 2008-107, Section 10.10(e). Specialty drugs in the following therapy categories will be affected:

- Anemia/neutropenia
- Anticoagulants
- Enzyme replacement
- Growth hormones
- Hemophilia
- Hepatitis
- HIV
- Hyperparathyroidism
- Immune deficiency
- Immune globulins

- Immunosuppressives
- Multiple sclerosis
- Oncology
- Osteoporosis
- Psoriasis
- Pulmonary
- Rheumatoid arthritis
- Other miscellaneous

The list of specialty drugs that are affected by this upper payment limit will be updated on a quarterly basis. This list will be available on DMA's website at <http://www.ncdhhs.gov/dma/pharmacy.htm>.

### **New Appeals Process Affecting Prior Authorized Medications**

The General Assembly, during its last session, enacted S.L. 2008-118 s. 3.13, effective July 01, 2008, that changes how Medicaid appeals are handled. As part of this change, beginning October 01, 2008, if a recipient does not meet criteria for coverage of a prior authorized medication, a notice which states the decision, citation that supports the decision, and recipient appeal rights will be mailed to the recipient. The recipient has 30 days from the date the notice is mailed to appeal the decision to the Office of Administrative Hearings.

If the recipient has been receiving the medication in the past 34 days AND files a request for an appeal, the recipient will be granted a prior authorization for the medication as a maintenance of service until their appeal has been heard and disposed. If the recipient has not been receiving the medication in the past 34 days, the recipient will not be eligible for the maintenance of service while they await their appeal to be heard and disposed. Additional information can be found at:

- N.C. D.M.A. Home Page which can be found online at <http://www.dhhs.state.nc.us/dma/>
- N.C. Medicaid Enhanced Pharmacy Program website which can be found online at <http://www.ncmedicaidpbm.com/>

### **Overrides for Monthly Supplies of Insulin**

It has recently been brought to N.C. Medicaid's attention that pediatric recipients have experienced difficulty obtaining insulin from their local pharmacies and this has resulted in unnecessary admissions to hospital emergency rooms. In these situations, the recipients had already received their 34-day supply of insulin for the month, but their insulin had been lost or the dose had changed, thus causing the recipient to need more insulin before the end of the month. N.C. Medicaid has measures in place for these types of situations when it is necessary for recipients to obtain additional supplies of critical medications such as insulin.

For non-controlled medications, overrides are available at the discretion of the pharmacist when he or she feels that it is in the best interest of the recipient to bill for additional medication. N.C. Medicaid relies on the judgment of pharmacists to ensure that these override codes are used only when necessary to allow for the continuation of optimal recipient care.

Please refer to Clinical Coverage Policy No. 9, Outpatient Pharmacy Program, on the DMA website at <http://www.ncdhhs.gov/dma/pharmacy.htm> for additional information on the use of override codes

### Deleted NDC Correction from CMS

CMS was notified by the FDA that the following NDC is not subject to the FDA's October 1, 2007 Federal Register notice. Therefore, CMS has reinstated the NDC as a covered outpatient drug effective as of **September 04, 2008**.

NDC	DRUG DESCRIPTION
00485005516	ED A HIST LIQUID

### Deleted NDCs from CMS

The following products do not meet the definition of covered outpatient drugs and are not rebate eligible. Therefore, they are being deleted from the CMS Master Drug Rebate (MDR) file of covered outpatient drugs effective as of **August 27, 2008**.

NDC	DRUG NAME
00095013004	ANAPLEX HD COUGH SYRUP
00095013016	ANAPLEX HD COUGH SYRUP
00109140980	HYDROCODONE BITARTRATE 3.5 MG/GUAIFENESIN 100 MG SYRUP
00131512964	CODIMAL DH SYRUP
00131512970	CODIMAL DH SYRUP
00131513464	CODICLEAR DH SYRUP
00131513470	CODICLEAR DH SYRUP
00225042045	KWELCOF
00472007716	HYCOSIN EXPECTORANT
00485005216	ED TLC LIQUID
00485005316	ED TUSS HC LIQUID
00485005516	ED A HIST LIQUID
00603111158	CODITUSS DH (AF) SYR
00603128358	H-C TUSSIVE-NR SYR 2.5-5-1MG/5ML
00603128454	HC TUSSIVE SYRUP
00603128458	HC TUSSIVE SYRUP
00603128558	H-C TUSSIVE D SYR
00603162558	QUINDAL-HD 2MG-7.5MG-2MG/5ML SYR
00603163658	QUINTEX HC SF DF AF
00603179958	TUSSICLEAR DH SYRUP 3.5MG-100MG/5ML
00603185354	VI-Q-TUSS LIQ
00603185358	VI-Q-TUSS LIQ
00682042016	MARCOF EXPECTORANT (REVISED FORMULA)

<b>NDC</b>	<b>DRUG NAME</b>
10914082004	HC 3.5 MG / GUAJ 300 MG SYRUP
10914083016	HC 2.5 MG / PE 5 MG / DBROM 1 MG SYRUP
10914098004	HYDROCODONE BITARTRATE 3.5 MG/GUAIFENESIN 100 MG SYRUP
12830071516	M-CLEAR
12830073316	M-END REFORMULATED
12830074216	M-CLEAR JR
12830075216	M-END MAX
14629030216	LEVAL 5.0
16477095601	DONATUSSIN DC SYRUP
23589000816	ENDAL HD SYRUP
50991032216	POLY-TUSSIN XP (NEW FORMULA)
50991060316	POLY-TUSSIN HD
50991070716	POLY-TUSSIN (NEW FORMULA)
50991071416	POLY HIST HC
50991072716	POLY-TUSSIN SYRUP (REVISED FORMULA)
50991092516	POLY-TUSSIN XP (EXPECTORANT)
52604020006	ENDAGEN-HD
52604030006	VANEX-HD
58177087707	HISTINEX HC
58177087712	HISTINEX HC
58177088103	CIII HYDROCODONE BITARTRATE/GUAIFENSIN
58177088107	CIII HYDROCODONE BITARTRATE/GUAIFENSIN
58177088112	CIII HYDROCODONE BITARTRATE/GUAIFENSIN
58177088307	HISTINEX PV
58177089007	CIII HYDRO-TUSSIN HD
58177091507	HYDRO-TUSSIN HC SYRUP (CIII)
58177091607	HYDRO-TUSSIN XP
58605053401	MAXI-TUSS HCX
58809044201	PHENA-HC
58809092901	VANACON
59702079916	ATUSS HS
59702081301	ATUSS HD CAPSULES
59702081401	ATUSS HX CAPSULES
63481023516	HYCOTUSS
64376003516	PHENYLEPHRINE HD (CIII)
64661004016	J-TAN D HC
65224061016	Z-COF HCX
66594011116	PRO-RED
66594022216	PRO-CLEAR
66813054516	ENTEX HC

<b>NDC</b>	<b>DRUG NAME</b>
66813093316	DYNEX HD
66813094016	BROVEX HC
66813098016	SYMTAN
66813098216	SYMTAN A
66992025016	VAZOTUSS HC
66993022255	BROMPLEX HD SYRUP 30/2/1.7MG
66993022257	BROMPLEX HD SYRUP 30/2/1.7MG
67204032016	ZYMINE LIQUID
67204039016	ZYMINE HC LIQUID
67537094016	BROMPHENIRAMINE/HYDROCODONE/PSE LIQUID
68025003216	ZOTEX HC
68032016516	HYDROCODONE BITARTRATE 4.5MG POTASSIUM GUAIACOLSUFONATE 300MG
68032016716	HYDROCODONE BITARTRATE 5MG PHENYLEPHRINE HYDROCHLORIDE 5MG
68047013116	ENDACOF-HC
68047013216	ENDACOF-XP
68047013316	ENDACOF-PLUS
68047013501	ENDACOF-TAB
68047017140	EXECOF-XP
68047018216	EXETUSS-HC
68047019016	DROTUSS
68047019116	DROTUSS-CP
68047020016	HYDROFED
68047022016	EXECLEAR
68047026016	PHENDACOF-HC
68047026116	PHENDACOF-PLUS
68308013404	D-TANN HC SUSPENSION
68308031016	NAZARIN HC LIQUID
68453012904	CODIMAL DH SYRUP CIII
68453012916	CODIMAL DH SYRUP CIII
68453013404	CODICLEAR DH SYRUP
68453013416	CODICLEAR DH SYRUP
68453014004	CODICLEAR DH SYRUP CIII
68453014016	CODICLEAR DH SYRUP CIII
68453014504	CODIMAL DH
68453014516	CODIMAL DH
68453086016	HISTUSSIN HC SYRUP CIII

The FDA has determined that the following drug is a DESI code 5; therefore, this drug will no longer be eligible for Medicaid coverage and rebate billing effective as of **September 15, 2008**.

NDC	DRUG NAME
52152006002	URSODIOL
52152006003	URSODIOL

### **FORM Reviews and Submission of FORM Fee**

This is a reminder that N.C. Medicaid requires that recipients receiving more than 11 prescriptions per month be evaluated as part of a Focused Risk Management (FORM) program. The first review must be completed within two (2) months of the recipient's identification for the program; subsequent reviews must be performed at least every three (3) months thereafter. Pharmacies participating in the FORM program are eligible for a quarterly FORM professional service fee upon completion of the FORM review. Pharmacy providers should submit FORM fees to N.C. Medicaid for reimbursement. A quarterly FORM fee of \$30.00 per provider per recipient will be paid to one pharmacy provider each quarter.

Program Integrity will perform audits to ensure adherence to this program. Failure to perform the required reviews and failure to have documentation of the review on file at the pharmacy will result in recoupment of the FORM fee payment as well as payment for all claims exceeding the limit of 11 prescriptions per month.

### **Clarification from CMS on the Use of Plain Paper for Computer-Generated Prescriptions**

Since issuing its last guidance on computer-generated prescriptions and the tamper-resistance prescription pad requirements, CMS has clarified that while special tamper-resistant paper can be used to achieve copy resistance, it is not necessary. Copy resistance can also be achieved with plain paper when utilizing two features that can be incorporated into plain paper computer-generated prescriptions. The first of these is microprinting, which is the use of very small font that is readable when viewed at 5x magnification or greater, and is illegible when copied. The second feature is a "Void" pantograph accompanied by a reverse "Rx" which causes a word such as "Void" or "Illegal" to appear when the prescription is photocopied.

In response to this recent clarification from CMS, DMA is updating its September 2007 guidance document as follows:

- Microprinting has been added as an acceptable feature to prevent unauthorized copying of a prescription.
- Features 1a and 1c have been revised by removing the word "entire" so that if the words "Void" or "Illegal" are present, they do not have to be across the entire face of the prescription.
- The word "copy" appearing across the front of the prescription blank when photocopied or scanned has been added as an acceptable feature to prevent unauthorized copying of a prescription.

The updated guidance document also reflects April 1, 2008 as the effective date for the first phase of implementation which was originally scheduled for October 1, 2007 before Congress delayed the effective date for six months.

For the updated guidance document and additional information on tamper-resistant prescription pads, please refer to DMA's website at

[http://www.dhhs.state.nc.us/dma/pharmacy/president\\_delay\\_pad\\_requirement.html](http://www.dhhs.state.nc.us/dma/pharmacy/president_delay_pad_requirement.html).

### **Enhanced Specialty Drug Discount Reimbursement Inquiries**

With the implementation of the new enhanced specialty drug discount on October 10, 2008, pharmacy providers may need to report specialty drug reimbursement issues to N.C. Medicaid. The State Maximum Allowable Cost (SMAC) inquiry worksheet will be revised so that issues with specialty drug reimbursement may also be reported on the same worksheet that SMAC drug reimbursement issues are reported. Pharmacists should fax the completed worksheet to the fax number on the worksheet (612-642-8931). The worksheet will be available on DMA's website at <http://www.ncdhhs.gov/dma/pharmacy/htm>.

### **False Claims Act Education Compliance for Federal Fiscal Year 2007**

Effective January 1, 2007, Section 6023 of the Deficit Reduction Act (DRA) of 2005 requires providers receiving annual Medicaid payments of \$5 million or more to educate employees, contractors, and agents about federal and state fraud and false claims laws and the whistleblower protections available under those laws.

Each year DMA will notify those providers who received a minimum of \$5 million in Medicaid payments during the last federal fiscal year (October 1 through September 30) with a reminder that they must submit a Letter of Attestation to Medicaid in compliance with the DRA. (A complete list of providers who meet this requirement is available on DMA's website at <http://www.ncdhhs.gov/dma/fca/falseclaimsact.html>.) This minimum amount may have been paid to one N.C. Medicaid provider number or to multiple Medicaid provider numbers associated with the same tax identification number. A separate notification will be mailed for each Medicaid provider number.

Providers must complete and submit a copy of the Letter of Attestation form within 30 days of the date of notification. Upon completion, submit the Letter to EDS by fax or by mail:

EDS  
Attn: PVS-False Claims Act  
P.O. Box 300012  
Raleigh NC 27622

Fax: Attn: PVS-False Claims Act at 919-851-4014

Compliance with Section 6023 of the DRA is a condition of receiving Medicaid payments. Medicaid payments will be denied for providers who do not submit a signed Letter of Attestation within 30 days of the date of notification. Providers may resubmit claims once the signed Letter is submitted to and received by EDS.

## Clinical Coverage Policies

The following new or amended clinical coverage policies are now available on DMA's website at <http://www.ncdhhs.gov/dma/mp/mpindex.htm>:

- General Coverage Policy A2, Over-the-Counter Medications
- 1A-20, Sleep Studies and Polysomnography Services
- 10B, Independent Practitioners

These policies supersede previously published policies and procedures. Providers may contact EDS at 1-800-688-6696 or 919-851-8888 with billing questions.

## Proposed Clinical Coverage Policies

In accordance with NCGS §108A-54.2, proposed new or amended Medicaid clinical coverage policies are available for review and comment on DMA's website at <http://www.ncdhhs.gov/dma/mp/proposedmp.htm>. To submit a comment related to a policy, refer to the instructions on the website. Providers without Internet access can submit written comments to the address listed below

Loretta Bohn  
Division of Medical Assistance  
Clinical Policy Section  
2501 Mail Service Center  
Raleigh NC 27699-2501

The initial comment period for each proposed policy is 45 days. An additional 15-day comment period will follow if a proposed policy is revised as a result of the initial comment period.

## Changes in Drug Rebate Manufacturers

The following changes have been made in manufacturers with Drug Rebate Agreements. They are listed by manufacturer's code, which are the first five digits of the NDC.

### Additions

The following labelers have entered into Drug Rebate Agreements and have joined the rebate program effective on the dates indicated below:

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
13436	Verus	09/12/2008
29300	Unichem Pharmaceuticals, Inc.	08/25/2008
42688	Almus Pharmaceuticals, USA LLC.	09/05/2008

**Terminated Labelers**

The following labelers will be terminated from the Medicaid Drug Rebate Program effective January 1, 2009:

Chemrich Laboratories Inc.,	(Labeler 10235)
Generamed, Inc.,	(Labeler 52569)
Carrington Laboratories, Inc.,	(Labeler 53303)
KVD Pharma, Inc,	(Labeler 68716)

**Voluntarily Terminated Labeler**

The following labeler has requested voluntary termination effective January 1, 2009:

Cardinal Health Singapore,. (Labeler 42115)

### Checkwrite Schedule

September 09, 2008	October 07, 2008	November 04, 2008
September 16, 2008	October 14, 2008	November 13, 2008
September 25, 2008	October 21, 2008	November 20, 2008
	October 30, 2008	

### Electronic Cut-Off Schedule

September 04, 2008	October 02, 2008	November 06, 2008
September 11, 2008	October 09, 2008	November 13, 2008
September 18, 2008	October 16, 2008	November 26, 2008
	October 23, 2008	

*Electronic claims must be transmitted and completed by 5:00 p.m. on the cut-off date to be included in the next checkwrite. Any claims transmitted after 5:00 p.m. will be processed on the second checkwrite following the transmission date. POS claims must be transmitted and completed by 12:00 midnight on the day of the electronic cut-off date to be included in the next checkwrite.*

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Thomas D'Andrea, R.Ph., MBA  
Chief, Pharmacy and Ancillary Services  
Division of Medical Assistance  
Department of Health and Human Services

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Ann Slade, R.Ph.  
Chief, Pharmacy Review Section  
Division of Medical Assistance  
Department of Health and Human Services

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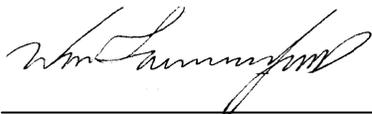
Lisa Weeks, PharmD, R.Ph.  
Outpatient Pharmacy Program Manager  
Division of Medical Assistance  
Department of Health and Human Services

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Sharon H. Greeson, R.Ph.  
Pharmacy Director  
EDS

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William W. Lawrence, Jr., M.D.  
Acting Director  
Division of Medical Assistance  
Department of Health and Human Services

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Melissa Robinson  
Executive Director  
EDS