



**An Information Service of the Division of Medical Assistance**

**North Carolina  
Medicaid Pharmacy  
Newsletter**

*Number 179*

*February 2010*

**In This Issue...**

**North Carolina Medicaid Preferred Drug List**  
**Additional Information on Prodigy Diabetic Supplies**  
**Addition of Pen Needles to Pharmacy Point-of-Sale**  
**Reinstatement of NDCs from CMS**  
**Update on Drug Interaction of Clopidogrel Bisulfate with Omeprazole**  
**Utilization of Acetaminophen Prescription Products Greater Than 4 Grams/Day**  
**Responding to DUR Alerts**  
**Early Refill Override Instructions**  
**HP Enterprise Services Address Change**  
**Changes in Drug Rebate Manufacturers**

## **North Carolina Medicaid Preferred Drug List**

DMA will establish a N.C. Medicaid Preferred Drug List (PDL) on March 15, 2010. The N.C. General Assembly [Session Law 2009-451, Sections 10.66(a)-(d)] authorized DMA to establish the PDL in order to obtain better prices for covered outpatient drugs through supplemental rebates. All therapeutic drug classes for which the drug manufacturer provides a supplemental rebate are considered for inclusion on the list with the exception of medications used for the treatment of human immunodeficiency virus (HIV) or acquired immune deficiency syndrome (AIDS).

Initially, when the PDL goes into effect, there will **not** be any changes in the drugs that are currently covered. **In the future**, selected therapeutic drug classes will be reviewed by DMA and the Pharmacy and Therapeutics Committee of the N.C. Physicians Advisory Group. Specific drug products within the selected therapeutic drug classes will be “preferred” based on therapeutic effectiveness, safety and clinical outcomes. Generally these drugs will not require prior authorization (PA) unless there are other clinical PA requirements such as step therapy or quantity limits.

“Non-preferred” drugs (drug products not included in the therapeutic drug classes listed on the PDL) will be available if prior authorization criteria are met. The prior authorization process will be the same process as it is today. If a prescriber deems that the patient’s clinical status necessitates therapy with a “non-preferred” drug, the prescriber will be responsible for initiating a prior authorization request.

For therapeutic drug classes that do not appear on the PDL, nothing has changed. Prescribers can prescribe drugs in these classes as in the past, unless existing prior authorization criteria exists.

The PDL is posted on the DMA Outpatient Pharmacy Program’s website at <http://www.ncdhhs.gov/dma/pharmacy/>.

## **Additional Information on Prodigy Diabetic Supplies**

The following additional information is provided regarding the Prodigy Diabetic Supply program:

### **Transition Period Extended Until April 16, 2010**

Effective February 16, 2010, there will be an additional 60 day extension period added to the North Carolina Medicaid Prodigy diabetic supplies transition phase.

- A one-time, per-recipient, per-product override will continue to be allowed for an additional 60 days
- The transition period will be extended until April 16, 2010
- No overrides will be allowed after April 16, 2010

### Addition of Safety Syringes and Safety Lancets

Effective February 26, 2010, the following safety syringes and safety lancets will be added to the North Carolina Medicaid Prodigy line of products under the pharmacy point-of-sale system. These products will be added to the Durable Medical Equipment (DME) program effective March 1, 2010.

Covered Product	Package Size	Unit Type	NDC-11
Prodigy Insulin Safety Syringe 29G 12.7 mm ½ (100ct)	100 ct Box	1 Box	08484990480
Prodigy Pressure Activated Safety Lancet 28G 1.8 mm (100ct)	100 ct Box	1 Box	08484990338

### Addition of Pen Needles to Pharmacy Point-of-Sale

Effective with date of service February 26, 2010, pen needles will be covered as an over-the-counter product in the N.C. Medicaid Outpatient Pharmacy Program. Recipients must have a prescription for the pen needles and there must be an insulin prescription on file within the last 90 days in order to bill using the pharmacy point-of-sale system. A National Drug Code (NDC) must be used when billing through point-of-sale. Rates apply to pen needles; therefore, no copayments or dispensing fees apply. Medicare Part D continues to cover pen needles for dual eligible recipients.

Pen needles do not have to be purchased at the same pharmacy as the insulin unless the patient is locked into a pharmacy. Recipients identified for the Focused Risk Management (FORM) Program who require more than 11 unduplicated prescriptions each month are restricted to a single pharmacy. In these cases, the pen needles must be purchased at the same pharmacy.

### Reinstatement of NDCs from CMS

After further review, CMS has withdrawn the DESI code of 5 for Analpram HC 2.5% lotion. As a result, this NDC is eligible for coverage under the Medicaid Drug Rebate Program and has been updated to reflect a DESI code of 2 as of **February 01, 2010**.

NDC	Drug Name
00496082904	Analpram HC 2.5% Lotion

### Update on Drug Interaction of Clopidogrel Bisulfate with Omeprazole

FDA is alerting the public to new safety information concerning an interaction between clopidogrel (Plavix), an anti-clotting medication, and omeprazole (Prilosec/Prilosec OTC), a proton pump inhibitor (PPI) used to reduce stomach acid. New data show that when clopidogrel and omeprazole are taken together, the effectiveness of clopidogrel is reduced. Patients at risk for

heart attacks or strokes who use clopidogrel to prevent blood clots will not get the full effect of this medicine if they are also taking omeprazole. The updated label for clopidogrel will contain details of new studies submitted by Sanofi-Aventis and Bristol-Myers Squibb, the manufacturer of Plavix (clopidogrel).

Omeprazole inhibits the drug metabolizing enzyme (CYP2C19) which is responsible for the conversion of clopidogrel into its active form (active metabolite). The new studies compared the amount of clopidogrel's active metabolite in the blood and its effect on platelets (anti-clotting effect) in people who took clopidogrel plus omeprazole versus those who took clopidogrel alone. A reduction in active metabolite levels of about 45% was found in people who received clopidogrel with omeprazole compared to those taking clopidogrel alone. The effect of clopidogrel on platelets was reduced by as much as 47% in people receiving clopidogrel and omeprazole together. These reductions were seen whether the drugs were given at the same time or 12 hours apart.

Other drugs that are potent inhibitors of the CYP 2C19 enzyme would be expected to have a similar effect and should be avoided in combination with clopidogrel. These include: cimetidine, fluconazole, ketoconazole, voriconazole, etravirine, felbamate, fluoxetine, fluvoxamine, and ticlopidine. Since the level of inhibition among other PPIs varies, it is unknown to what amount other PPIs may interfere with clopidogrel. However, esomeprazole, a PPI that is a component of omeprazole, inhibits CYP2C19 and should also be avoided in combination with clopidogrel. FDA is aware there are studies, such as the Clopidogrel and Optimization of Gastrointestinal Events (COGENT) study, that might provide information about the effect of this interaction on clinical outcome. Although the FDA has not fully reviewed the study results, the applicability of these data is limited because of the study design and follow-up. Therefore, based on the current scientific information, the clopidogrel label has been updated with new warnings on omeprazole and other drugs that inhibit the CYP2C19 enzyme that could interact with clopidogrel in the same way. In addition, the manufacturer of Plavix (clopidogrel) is conducting follow-up studies to explore this and other drug interactions.

### **Considerations for Healthcare Professionals**

- The concomitant use of omeprazole and clopidogrel should be avoided because of the effect on clopidogrel's active metabolite levels and anti-clotting activity. Patients at risk for heart attacks or strokes, who are given clopidogrel to prevent blood clots, may not get the full protective anti-clotting effect if they also take prescription omeprazole or the OTC form (Prilosec OTC).
- Separating the dose of clopidogrel and omeprazole in time will not reduce this drug interaction.
- Other drugs that should be avoided in combination with clopidogrel because they may have a similar interaction include: esomeprazole (Nexium), cimetidine (which is available by prescription Tagamet and OTC as Tagamet HB), fluconazole (Diflucan), ketoconazole (Nizoral), voriconazole (VFEND), etravirine (Intelence), felbamate (Felbatol), fluoxetine (Prozac, Serafem, Symbyax), fluvoxamine (Luvox), and ticlopidine (Ticlid).
- At this time the FDA does not have sufficient information about drug interactions between clopidogrel and PPIs other than omeprazole and esomeprazole to make specific recommendations about their co-administration. Healthcare professionals and patients should consider all treatment options carefully before beginning therapy.

- There is no evidence that other drugs that reduce stomach acid, such as most H2 blockers ranitidine (Zantac), famotidine (Pepcid), nizatidine (Axid), except cimetidine (Tagamet and Tagamet HB - a CYP2C19 inhibitor) or antacids interfere with the anti-clotting activity of clopidogrel. Ranitidine and famotidine are available by prescription and OTC to relieve and prevent heartburn and antacids are available OTC to relieve heartburn.
- Talk with your patients about the OTC medicines they take. Be aware that patients may be taking non - prescription forms of omeprazole and cimetidine.

The FDA will continue to investigate other drug interactions with clopidogrel.

Source: Available at: [www.fda.gov](http://www.fda.gov). Accessed January 7, 2010.

### **Utilization of Acetaminophen Prescription Products Greater Than 4 Grams/Day**

Acetaminophen is an effective agent for the relief of both acute and chronic pain. Acetaminophen is available both over-the-counter and as a prescription product often combined with opioid analgesics. Acetaminophen has a history of being a safe and effective drug; however, unintentional or intentional misuse of the drug is the number one cause of acute hepatic failure in the United States leading to liver transplantations or even death. The maximum daily dose for adults and adolescents is 1000 mg/dose orally/rectally or 4 g/day orally/rectally for most formulations. For the extended-release oral product, 1300 mg/dose, with the same overall daily dose limits as other formulations is the maximum<sup>1</sup>.

In a 2003 cross-sectional study with an adult, general internal medicine population it was reported that eighty percent of patients had recent acetaminophen use. However, patient knowledge of the maximum daily dose and toxicities of acetaminophen were poor. Seventy-one percent of patients correctly identified Tylenol as containing acetaminophen but less than fifteen percent recognized products such as Darvocet, Vicodin, Tylox, Percocet, and Lorcet as containing acetaminophen. These findings indicate a need for physicians and pharmacists to educate their patients on safe acetaminophen use<sup>2</sup>.

#### **Based on a recent N.C. Medicaid Drug Utilization Review (DUR) intervention looking at acetaminophen (APAP) utilization, the following are considerations for Healthcare Professionals when prescribing/dispensing products containing APAP:**

- Educate patients on OTC and prescription products containing acetaminophen.
- Advise caution regarding combining products containing APAP.
- The acetaminophen maximum daily dose for adults and adolescents is 4 g/day orally/rectally.

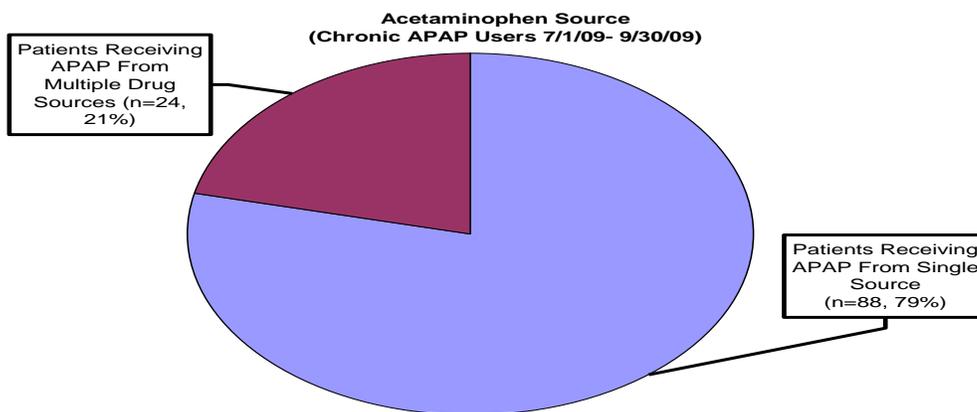
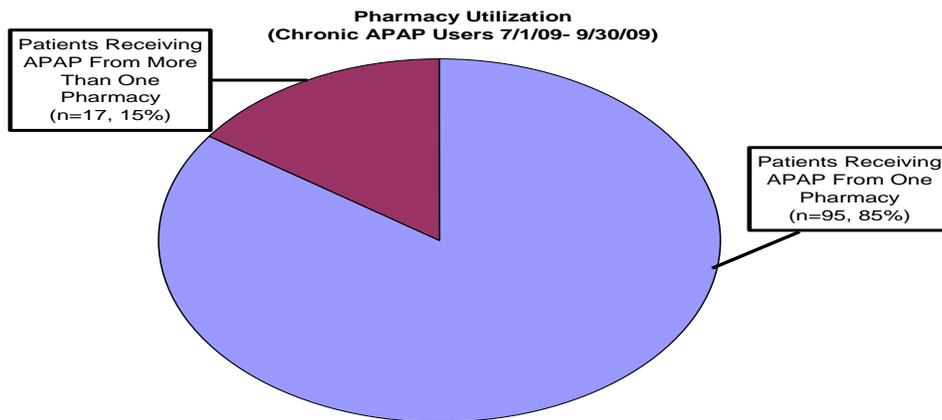
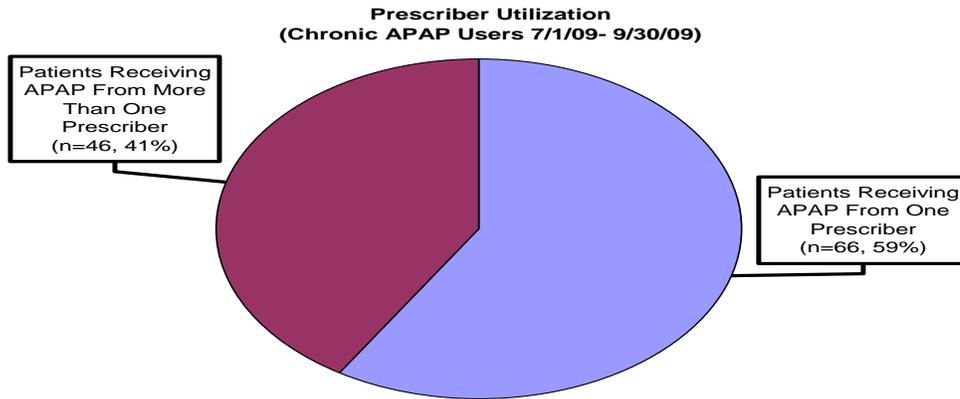
The following is from the recent DUR APAP intervention.

---

<sup>1</sup> Acetaminophen. Available at [www.clinicalpharmacology.com](http://www.clinicalpharmacology.com). Accessed December 10, 2009.

<sup>2</sup> Stumpf JL, Skyles AJ, Cesar A, et al. Knowledge of Appropriate Acetaminophen Doses and Potential Toxicities in an Adult Clinic Population. JAPhA. 2007; 47: 35-41.

**Drug Utilization Review Intervention:** N.C. Medicaid patients who have used acetaminophen products greater than thirty days who have had a prescription(s) for greater than 4g/day were selected for review (n=880). The patients were then narrowed down to those who chronically exceed 4g/day of acetaminophen (n=112).



## Responding to DUR Alerts

DUR processing begins after the claim is considered payable. Incoming drug claims are compared to the patient's pharmacy claims history files to detect potential therapeutic problems. DUR alert messages are returned to the pharmacist for problems discovered by this review. The process is as follows:

- Pharmacist receives DUR alert message(s) on computer screen; claim is rejected for DUR
- Pharmacist reviews and resolves identified DUR conflict(s) by contacting the prescriber, talking with the patient, and/or using other resources or professional judgment
- If pharmacist decides not to dispense the prescription, the pharmacist accepts the reject.
- Pharmacist does not resubmit claim and does not receive payment.
- If pharmacist decides to resolve and dispense the prescription, the pharmacist resubmits the correct claim with a DUR Conflict code, DUR Intervention code, and DUR Outcome code
- Pharmacist receives a paid response if the prescription was filled with DUR documentation.

DUR alert messages contain standardized codes and language, but may be displayed in various ways, depending on the pharmacy software in use. The **content of the DUR Alert message** includes:

### Conflict Code

This two-character alphabetic code identifies the conflict between the submitted drug claim and information in the patient's history file or predetermined screening criteria.

### Clinical Significance/Severity Index Code

This numeric value indicates the database-assigned significance of the conflict. 0= Not applicable, 1= Major, 2= Moderate, 3 = Minor

### Other Pharmacy Indicator

This numeric value identifies the originating location of the history claim with which the submitted drug claim conflicts. 0= Not applicable, 1= Your Pharmacy, 3= Other Pharmacy

### DUR Conflict Codes, Intervention and Outcome Codes

#### NCPDP DUR CODES

##### Conflict Codes from Medicaid

##### Additional Message Text

DD - Drug-Drug Interaction

“Drug Name with Strength” of interacting drug

TD - Therapeutic Duplication

“Drug Name with Strength duplicates this Rx”

ER - Overuse Precaution

“Refill is \_\_\_\_ days early”

LR - Underuse Precaution

“Refill is \_\_\_\_ days late”

DC - Drug-Disease Precaution	“Condition contraindicates use of prescribed drug”
LD - Low Dose Alert	“Minimum dose, Maximum dose, dose unit”
HD - High Dose Alert	“Minimum dose, Maximum dose, dose unit”

Intervention Codes from Pharmacist

- M0 - Prescriber Consulted
- P0 - Patient Consulted
- R0 - Pharmacist Consulted Other Source
- 00 - No Intervention
- Blank Not specified

Outcome Codes from Pharmacist

- 1A - filled, False Positive
- 1B - Filled Prescription as is
- 1C - Filled with different dose
- 1D - Filled with different directions
- 1E - Filled with different drug
- 1F - Filled with different quantity
- 1G - Filled with prescriber approval
- 2A - Prescription not filled
- 2B - Prescription not filled - directions clarified

**Early Refill Override Instructions**

In addition to the instructions above, an early refill alert also requires an approved reason code which should be entered in the prescription clarification field:

**03=Vacation Supply-** To be used if the patient is going out of town and needs medication refilled early.

**04=Lost Prescription-** To be used if the patient has lost their medication

**05=Therapy Change-** To be used if the dosage is changed on a current medication.

**There are no approved reasons for early refill overrides on controlled substances.**

**Example of Early Refill Process:**

Once the pharmacist has verified with the patient the reason for the early refill, the following should occur. After receiving the alert the pharmacist will enter the following DUR override: CC = ER, IC = P0, OC = 1B. In addition to this, one of the reason codes listed above will also need to be indicated in the prescription clarification field. If any fields are left blank, the claim will deny.

## HP Enterprise Services Address Change

Beginning January 11, 2010, certified mail and UPS or Federal Express deliveries must be sent to HP at the following new address.

HP Enterprise Services  
Suite 401  
2610 Wycliff Road  
Raleigh, NC 27607

Mail sent to any of HP's post office box addresses will not be affected.

## 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.

### Addition

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

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
42806	Epic Pharma LLC	01/26/2010
43378	Codadose Incorporated	01/15/2010
44946	Sancilio & Company, Inc	01/26/2010
45043	Manchester Pharmaceuticals, Inc	01/14/2010
47783	Dyax Corp	01/28/2010
47781	Alvogen Inc	01/29/2010
59987	Valeant/Dow/Descartes Acquisition Corp	01/19/2010

### Terminated Labeler

The following labeler will be terminated from the Medicaid Drug Rebate Program effective April 1, 2010:

Dabur Pharma US, Inc (Labeler 10518)

### Voluntarily Terminated Labeler

The following labeler has requested voluntary termination effective April 1, 2010:

SkinMedica, Inc (Labeler 67402)

### Checkwrite Schedule

February 02, 2010	March 02, 2010	April 06, 2010
February 09, 2010	March 09, 2010	April 13, 2010
February 17, 2010	March 16, 2010	April 22, 2010
February 25, 2010	March 25, 2010	April 25, 2010

### Electronic Cut-Off Schedule

January 28, 2010	February 25, 2010	April 01, 2010
February 04, 2010	March 04, 2010	April 08, 2010
February 11, 2010	March 11, 2010	April 15, 2010
February 18, 2010	March 18, 2010	

*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.*

---

**Lisa Weeks, PharmD, R.Ph.**  
Chief, Pharmacy and Ancillary Services  
Division of Medical Assistance  
Department of Health and Human Services

**Glenda Adams, PharmD.**  
Outpatient Pharmacy Program Manager  
Division of Medical Assistance  
Department of Health and Human Services

**Craig L. Gray, MD., MBA., JD**  
Director  
Division of Medical Assistance  
Department of Health and Human Services

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

**Sharon H. Greeson, R.Ph.**  
Pharmacy Director  
HP Enterprise Services

**Melissa Robinson**  
Executive Director  
HP Enterprise Services

---