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### **Transition Period for Oral Inhaled Corticosteroids, Leukotrienes, and Statins**

The six-month transition period for oral inhaled corticosteroids and corticosteroid combination products, leukotrienes, and statins, which includes Zetia, ended on March 15, 2011.

This transition period was provided to allow prescribers time to complete the necessary prior approval form or to transition to a preferred product if the patient does not meet the clinical criteria.

### **Coverage of Prescription Vitamins and Mineral Products for N.C. Medicaid Recipients**

Effective April 13, 2011, N.C. Medicaid will discontinue coverage of all legend vitamins and mineral products with the exception of prenatal vitamins and fluoride. N.C. Medicaid will continue to cover legend prenatal vitamins and fluoride products for Medicaid recipients. Vitamins and minerals, including prenatal vitamins and fluoride products, will no longer be covered for dual-eligible recipients.

### **HIPAA 5010 and NCPDP D.0 Implementation**

In accordance with 45 CFR Part 162 – Health Insurance Reform; Modifications to the Health Insurance Portability and Accountability Act (HIPAA); Final Rule, HIPAA-covered entities, which include state Medicaid agencies, must adopt modifications to the HIPAA required standard transactions by January 1, 2012. The modifications are to the HIPAA named transactions to adopt and implement ASC X12 version 5010 and NCPDP Telecommunication version D.0.

N.C. Medicaid will be implementing the HIPAA requirements for the 5010 transactions within the MMIS+ claims processing system. DMA will notify providers through upcoming Medicaid bulletins as the HIPAA 5010 implementation efforts progress.

## Policy Implementation: Off Label Antipsychotic Monitoring in Children through Age 17

### Phase One Implementation: Children 0 through 12 years of Age - Start Date April 12, 2011

The use of antipsychotic medications by children is an issue confronting parents, other caregivers, health care professionals, and related organized health care agencies across the United States. It is recognized that many antipsychotic medications do not have Food and Drug Administration (FDA) approved labeling for use in children. The risk for a variety of significant side effects related to the use of antipsychotic medications appears to be significant for children and adolescents. Due to well-documented safety considerations and limited efficacy information on the use of antipsychotic agents in children, DMA will implement a policy titled *Off Label Antipsychotic Monitoring in Children through Age 17*. The policy creates an opportunity to gather information about antipsychotic prescribing trends within the child and adolescent Medicaid population of North Carolina.

In accordance with the policy, DMA, in partnership with Community Care of North Carolina, will maintain a registry for providers to document the use of antipsychotic therapy in Medicaid-eligible children age 17 and under. This registry is supported by an advisory panel consisting of child psychiatrists from North Carolina's four medical universities. The registry, named **A+KIDS** (Antipsychotics-Keeping It Documented for Safety), encourages the use of appropriate baseline and follow-up monitoring parameters to facilitate the safe and effective use of antipsychotics in this population. The registry will be implemented in phases according to the age of the child for whom the antipsychotic is prescribed. Phase one for Medicaid eligible children 12 years of age or younger will begin April 12, 2011. The subsequent phase for the 13 through 17 age group will occur under the same guidelines at a later date. Providers will receive notification of the start date for phase two.

Objectives of the **A+KIDS** registry include improvement in the use of evidence-based safety monitoring for patients for whom an antipsychotic agent is prescribed; reduction of antipsychotic polypharmacy; and reduction of cases in which the FDA maximum dose is exceeded. Data elements collected within the registry reflect a generally accepted monitoring profile for the safety and efficacy follow-up of the prescribed antipsychotic pharmacotherapy. The prescriber should provide safety-monitoring documentation for any of the following occurrences:

- The antipsychotic is prescribed for an indication that is not approved by the FDA.
- The antipsychotic is prescribed at a higher dosage than approved for a specific indication by the FDA.
- The prescribed antipsychotic will result in the concomitant use of two or more antipsychotic agents.

#### About the A+KIDS Registry

Prescribers are directed to the **A+KIDS** website ([www.documentforsafety.org](http://www.documentforsafety.org)) to register as an **A+KIDS** provider to enable access to the online registry or to learn more about this initiative. Pharmacy providers are encouraged to visit the website to understand how the policy may impact pharmacy claims processing for antipsychotic medications.

Phase one of the registry process will capture demographics and brief clinical information. The information can be submitted electronically through the **A+KIDS** website ([www.documentforsafety.org](http://www.documentforsafety.org)) or by completing a form to submit by fax to ACS at 866-246-8507.

The form will be available on the DMA outpatient pharmacy website ([www.ncdhhs.gov/dma/pharmacy](http://www.ncdhhs.gov/dma/pharmacy)) and the A+KIDS website ([www.documentforsafety.org](http://www.documentforsafety.org)). Using the fax method to provide information will result in a three-month approval period. Faxed forms missing essential information cannot be processed and will be returned to the prescriber. When information is provided electronically through the registry, approval periods from 3 to 12 months are possible depending on case specific clinical variables.

Providers can complete registry information in advance for patients. In late March, staff from Community Care of North Carolina began contacting prescribers to educate about the registry and to inform about the preregistration process. Technical support is available for providers Monday through Friday from 8am to 5pm by calling the registry toll free number 855-272-6576.

### **Pharmacy Override Protocol**

Point of sale (POS) overrides are available for occurrences where the prescriber has not provided registry documentation either electronically or by fax for the recipient. Each override will apply to all claims for antipsychotic medication(s) on the same date of service. The message "Safety documentation requested. Prescriber go to [www.documentforsaftey.org](http://www.documentforsaftey.org) or call ACS 866-246-8505" will return to the pharmacy for antipsychotic claims for a recipient without registry documentation. The claim will not process successfully. A POS override should be utilized for rejected claims if timely A+KIDS registration by the prescriber does not occur. **A "1" in the PA field (461-EU) or a "2" in the submission clarification field (420-DK) will override the PA edit.** Patients should not be denied their antipsychotic medication(s) in response to the safety documentation requested message. The prescriber of the antipsychotic medication should be alerted when an override is used, and the language returned in the original POS message regarding the safety documentation request should be shared with him/her. Use of overrides is not restricted during the period from April 12, 2011 to July 12, 2011.

After July 12, 2011, each patient has available two POS override opportunities per 365 calendar days for two unique dates of service. If a third override is attempted, the message "Override limit exceeded. Prescriber go to [www.documentforsafety.org](http://www.documentforsafety.org) or call ACS 866-246-8505" will return to the pharmacy. This message cannot be overridden. This alert indicates the prescriber should provide registry documentation for the recipient in order for successful claims processing to result, and this information should be shared with the prescriber.

Many resources are available to assist providers with understanding the policy and registry. Technical support is available to assist providers with registration and questions and can be accessed by calling the toll free number, 855-272-6576, found on the website. Community Care of North Carolina network psychiatrists and pharmacists are available to educate about the registry. Additionally, help may be obtained by calling the ACS helpline at 866.246.8505. DMA assistance with understanding the policy and registry is available by contacting the outpatient pharmacy program at 919.855.4300.

## Changes in Drug Rebate Manufacturers

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

### Addition

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

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
35573	Burel Pharmaceuticals	03/21/2011
49401	Human Genome Science Inc	03/29/2011
49908	Rochester Pharmaceuticals	03/21/2011
50742	Ingenus Pharmaceuticals LLC	03/25/2011
51167	Vertex Pharmaceuticals Inc	03/14/2011
52536	Wilshire Pharmaceuticals Inc	03/09/2011
52547	Pediatrx, Inc	03/17/2011

### Checkwrite Schedule

March 03, 2011	April 05, 2011	May 05, 2011
March 08, 2011	April 12, 2011	May 11, 2011
March 15, 2011	April 21, 2011	May 18, 2011
March 24, 2011		May 27, 2011

### Electronic Cut-Off Schedule

February 24, 2011	March 31, 2011	April 29, 2011
March 03, 2011	April 07, 2011	May 06, 2011
March 10, 2011	April 14, 2011	May 13, 2011
March 17, 2011		May 20, 2011

*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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