



# ALABAMA MEDICAID PHARMACIST

Published Quarterly by Health Information Designs, Inc., Fall 2011

A Service of Alabama Medicaid

## PDL Update

Effective October 1, 2011, the Alabama Medicaid Agency will:

1. Limit the number of brand name prescriptions to four per month per recipient. There will not be a limit on the number of covered generic or over-the-counter prescriptions a recipient may receive. This limitation does not apply to children under the age of 21 or to recipients living in nursing facilities. Medicaid will continue to allow for prescriptions to exceed the four brand limit for antipsychotic and anti-retroviral medications; however, there will be no instance where the limit may exceed ten brand name drugs per month per recipient.
2. No longer require prior authorization (PA) for payment of generic pantoprazole.

Please fax all prior authorization and override requests

*directly* to Health Information Designs at

800-748-0116. If you have questions, please call 800-748-0130 to speak with a call center representative.

Effective October 3, 2011, the Alabama Medicaid Agency will require prior authorization (PA) of all antipsychotic medications utilizing the electronic PA process. The PA process will affect all recipients (adults and children) as well as all antipsychotics (brand and generic, first and second generation). The PA criteria for this drug class can be found on the Agency's website at [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov). Claims not approved through the electronic PA process at the pharmacy point of sale will require a manual PA form to be submitted; prescribers will receive automatic fax notification if additional medical justification is required.

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## FDA Mandates Major Change for Manufacturers of Prescription Pain Relievers

On January 13th, 2011, the FDA announced that it is asking manufacturers of prescription combination pain products that contain acetaminophen to limit the amount of acetaminophen to no more than 325mg per dosage unit in response to the high rates of acute liver injury and death associated with acetaminophen overdose. The FDA is also requiring new labeling that warns of the risk of severe liver injury if too much of the ingredient is taken or consumed with alcohol. This plan, that is to be implemented over the next three years, affects dozens of prescription pain products that contain acetaminophen in combination with other drugs such as hydrocodone, oxycodone, and codeine. However, over-the-counter products containing acetaminophen will *not* be affected by the plan.

*FDA asking manufacturers to limit amount of acetaminophen to no more than 325mg per dosage unit.*

Acetaminophen is widely accepted as a safe and effective pain reliever and fever reducer when taken at the recommended doses. However, because it is present in many prescription pain relievers, over-the-counter pain relievers, cold medicines, and even sleep aids, an individual could easily take over the 4000mg maximum daily dose without even knowing it.

According to a report published by the CDC, the number one cause of the nearly 1,600 cases of acute liver failures reported in the U.S. every year is acetaminophen toxicity. One study estimated that there are over 400 deaths each year related to acetaminophen induced liver failure, at least 100 of these being unintentional. Considering the fact that hydrocodone/acetaminophen products (brand names include Lortab<sup>®</sup>, Vicodin<sup>®</sup>, and Lorcet<sup>®</sup>) have topped the 200 most prescribed drugs list since 1997 and that current formulations of opioid/acetaminophen

combos may contain anywhere from 250mg to 750mg of acetaminophen per tablet, it is probably not surprising that the FDA has finally decided to take action.

Rest assured that current recommended dosing instructions and quantity limits for the affected products will not change as a result of the mandate, and there is not expected to be any drug shortages while the plan is being rolled out.

### References:

1. Food and Drug Administration Web site. <http://www.fda.gov> Accessed July 18, 2011.
2. Clinical pharmacology. <http://clinicalpharmacology-ip.com.ezproxy.samford.edu/Default.aspx>. Accessed July 18, 2011.
3. Nourjah et al. Estimates of Acetaminophen (Paracetamol)-associated overdoses in the United States. *Pharmacoepidemiol Drug Safety*. 2006 Jun; 15(6).
4. Bower WA, Johns M, Margolis, HS, Williams IT, Bell B. Population-Based Surveillance for Acute Liver Failure. *Am J Gastroenterol*. 2007; 102:2459-63.



## FDA Requiring New Dosing Limitations and Contraindications for Simvastatin

The FDA is recommending that the dose of simvastatin be limited to 80 mg because of the increased risk of muscle damage. In 2010, over 2 million patients in the United States were prescribed a product containing simvastatin 80 mg. Simvastatin is available as Zocor<sup>®</sup> and in the combination products Vytorin<sup>®</sup> and Simcor<sup>®</sup>. Vytorin<sup>®</sup> contains 10, 20, 40, or 80 mg of simvastatin and Simcor<sup>®</sup> contains 20 or 40 mg of simvastatin.

The FDA based their recommendations on the results of the Study of the Effectiveness of Additional Reductions in Cholesterol and Homocysteine (SEARCH) trial and on analyses of the FDA's Adverse Event Reporting System (AERS) database. SEARCH was a seven-year, randomized, double-blind trial which compared the efficacy and safety of simvastatin 20 mg to simvastatin 80 mg, with or without vitamin B12 or folate, in survivors of myocardial infarction. Although the trial found simvastatin 80 mg to reduce LDL cholesterol more than simvastatin 20 mg, it also found that more participants taking simvastatin 80 mg developed myopathy and rhabdomyolysis. The risk of myopathy and rhabdomyolysis was found to be highest during the first 12 months of use.

The FDA is recommending that patients be maintained on simvastatin 80 mg only if they have been taking this dose for 12 or more months without evidence of muscle toxicity. New patients should not be started on simvastatin 80 mg. If a patient does not meet their LDL-C goal on simvastatin 40 mg, an alternative statin with greater LDL-lowering ability should be used. The FDA has updated drug labels of simvastatin, Vytorin<sup>®</sup>, and Simcor<sup>®</sup> to

reflect the new dosing restrictions. Prescribers should be aware of other medications their patients are taking and decrease the dose of simvastatin accordingly. Drugs such as amiodarone (Cordarone<sup>®</sup>, Pacerone<sup>®</sup>), verapamil (Calan<sup>®</sup>, Verelan<sup>®</sup>), and diltiazem (Cardizem<sup>®</sup>, Cartia<sup>®</sup>) should only be taken with 10 mg of simvastatin daily. Amolodipine (Norvasc<sup>®</sup>) and ranolazine (Ranexa<sup>®</sup>) should not be taken with more than 20 mg of simvastatin daily.

Physicians and pharmacists should monitor their patients closely to avoid any unnecessary muscle damage due to high doses of simvastatin or drug interactions.

### References:

1. FDA. FDA announces new safety recommendations for high-dose simvastatin. June 8, 2011. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm258338.htm>. [Accessed August 11, 2011].
2. New restrictions, contraindications, and dose limitations for Zocor<sup>®</sup> (Simvastatin). Pharmacist's Letter/Prescriber's Letter 2011; 27(7): 270712.
3. Zocor<sup>®</sup> [package insert]. Whitehouse Station, NJ: Merck & Co., Inc.; 2011.
4. Simcor<sup>®</sup> [package insert]. North Chicago, IL: Abbot Laboratories; 2011.
5. Vytorin<sup>®</sup> [package insert]. North Wales, PA: Merck/Schering-Plough Pharmaceuticals; 2011.

## Pharmacy DME Providers

Pharmacy providers that are enrolled with Alabama Medicaid as Durable Medical Equipment (DME) providers must follow DME billing procedures to receive reimbursement for services provided to Alabama Medicaid recipients. When billing for DME items and supplies you must bill with the correct HCPC code, **not** NDC codes.

If you are having difficulty submitting your claims for diabetic strips (A4253) and lancets (A4259) or any other DME items or supplies, please contact your HP provider representative for assistance. Your HP provider representatives are Nawanya Stroud (334-215-4161), Hayley Lavender (334-215-4158), and Shemekia Pena (334-215-4199). Your HP provider representatives can assist you with any DME billing problems you may have. HP provider representatives also make onsite visits for purposes of training to any DME company enrolled as an Alabama Medicaid provider located in the state Alabama, or within a thirty mile radius of the Alabama state line.

If you have any questions regarding DME policies or DME coverage issues, please contact the Pharmacy DME Unit at 334-353-4753 or 334-353-4756.

## Tamiflu Suspension Now Available in New Strength

As the 2011 flu season is approaching, the use of Tamiflu<sup>®</sup> will begin to increase. Genentech announced that Tamiflu<sup>®</sup> suspension will be reduced from 12 mg/mL to 6 mg/mL. Tamiflu<sup>®</sup> 12 mg/mL will no longer be manufactured. Genentech began distribution of the new concentration of Tamiflu<sup>®</sup> suspension in July.

Even though the formulation of Tamiflu<sup>®</sup> suspension did not change, several other changes were made. Genentech is expecting the lower concentration of the suspension to result in less foaming. The oral dispenser is now labeled in milliliters instead of milligrams in an effort to simplify prescribing and dosing. The final volume of Tamiflu<sup>®</sup> has increased from 25 mLs to 60 mLs.

It is important for healthcare providers to be aware of the new concentration of Tamiflu<sup>®</sup>. Physicians should include the new concentration and dose in milliliters on all prescriptions for Tamiflu<sup>®</sup> suspension. Pharmacists should be aware of the concentration they are dispensing as they may have both concentrations in stock.

1. Tamiflu<sup>®</sup> [package insert]. South San Francisco, CA: Genentech USA, Inc.; 2011.
2. Tamiflu<sup>®</sup> New Strength. 2011. Available from: [http://www.tamiflu.com/pdf/Tamiflu\\_Oral\\_Suspension.pdf](http://www.tamiflu.com/pdf/Tamiflu_Oral_Suspension.pdf). [Accessed August 12, 2011].



## Flu Vaccine Reimbursement Continues for Medicaid-Enrolled Providers



The pharmacy flu vaccines program launched by Alabama Medicaid in November 2009 will continue for the upcoming 2011-2012 flu season. Medicaid-enrolled pharmacy providers will be reimbursed for administration of the influenza vaccine to Medicaid-eligible patients 19 years and older.

Pharmacies will be reimbursed for administration of the vaccine as well as the vaccine itself. The vaccine for the 2011-2012 flu season will be the same as last years' vaccine, protecting against the seasonal influenza virus and the H1N1 virus. Pharmacies should submit the NDC of 99999-9999-10 on a pharmacy claim for the administration of the vaccine for reimbursement. Pharmacies will be reimbursed \$5 per administration with no dispensing fee or co-pay applied. Claims should be submitted with a dispensed quantity of 1 for vaccine administration. There will be a maximum quantity of 1 injection allowed per recipient per year for each vaccine.

Pharmacy providers are required to inform (via phone, fax, email, mail) each recipient's Primary Medical Provider (PMP) upon administration of the vaccine. Documentation of communication to the recipient's PMP must be kept on file at the pharmacy. If the PMP is unknown, the pharmacy may call the Alabama Medicaid Automated Voice Response System (AVRS) at 1-800-727-7848 to obtain the PMP information. A suggested Immunization Provider Notification Letter, which can be used to notify the PMP, can be found on Alabama Medicaid's website at [http://medicaid.alabama.gov/documents/5.0 Resources/5.4 Forms Library/5.4.5 Pharmacy Services/5.4.5 Immunization Provider Notification Letter 12-1-10.pdf](http://medicaid.alabama.gov/documents/5.0_Resources/5.4_Forms_Library/5.4.5_Pharmacy_Services/5.4.5_Immunization_Provider_Notification_Letter_12-1-10.pdf).

Alabama State Board of Pharmacy law and regulation should be followed regarding dispensing and administration of legend drugs/vaccines.

### References:

1. FDA. FDA approves vaccines for the 2011-2012 influenza season. July 18, 2011. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm263319.htm> [Accessed August 15, 2011].
2. FDA. Influenza Virus Vaccine for the 2011-2012 Season. August 10, 2011. Available from: <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Post-MarketActivities/LotReleases/ucm262681.htm> [Accessed August 15, 2011].
3. Alabama Medicaid. Flu vaccines reimbursement continues for Medicaid-enrolled providers. September 1, 2010. Available from: [http://medicaid.alabama.gov/documents/4.0 Programs/4.5 Pharmacy Services/4.5.15 Vaccine/4.5.15 Flu Vaccines Reimbursement 9-10.pdf](http://medicaid.alabama.gov/documents/4.0_Programs/4.5_Pharmacy_Services/4.5.15_Vaccine/4.5.15_Flu_Vaccines_Reimbursement_9-10.pdf) [Accessed August 15, 2011].

## Palivizumab Criteria for 2011-2012 RSV Season

The Alabama Medicaid Agency has updated the prior authorization criteria for palivizumab during the 2011-2012 RSV season. Below are some highlights for the season. Complete criteria can be found on the website at the following link:

[http://medicaid.alabama.gov/CONTENT/4.0\\_Programs/4.5.0\\_Pharmacy/4.5.14\\_Synagis.aspx](http://medicaid.alabama.gov/CONTENT/4.0_Programs/4.5.0_Pharmacy/4.5.14_Synagis.aspx)

- The approval time frame for palivizumab will begin October 1, 2011 and will be effective through March 31, 2012.
- Up to five doses will be allowed per recipient in this timeframe. Some recipients may only receive up to a maximum of 3 doses, depending on the gestational and chronological age.
- There are no circumstances that will result in approval of a sixth dose.
- If a dose was administered in an inpatient setting, the date the dose was administered must be included on the request form.
- For approval of requests, the recipient must meet gestational and chronological age requirements. In order to meet chronological age requirements, the recipient must not exceed the specified age at the start of the RSV season.
- Prescribers, not the pharmacy, manufacturer or any other third party entity, are to submit requests for palivizumab on a separate prior authorization form (Form 351) **directly** to Health Information Designs and completed forms will be accepted beginning September 1, 2011 (for an October 1 effective date).
- Stamped or copied physician signatures will not be accepted and will be returned to the provider.
- A copy of the hospital discharge summary from birth or documentation of the first office visit with pertinent information (gestational age, diagnosis, etc.) is required on all palivizumab PA requests.
- If approved, each subsequent monthly dose will require submission of the recipient's current weight and last injection date and may be faxed to HID by the prescribing physician or dispensing pharmacy utilizing the original PA approval letter.
- Letters will be faxed to both the prescriber and the dispensing pharmacy notating approval or denial.

### Criteria

Alabama Medicaid follows the 2009 updated American Academy of Pediatrics (AAP) guidelines regarding palivizumab utilization. Additional questions regarding palivizumab criteria can be directed to the Agency's Prior Authorization contractor, Health Information Designs at 1-800-748-0130.

## Correct prescribing physician license number or NPI required on all pharmacy claims

Pharmacies participating in the Alabama Medicaid program are required to use the prescribing physician's NPI or license number when filing a claim with the Agency. A recent review of pharmacy billing practices found that numerous pharmacies are using an incorrect prescribing physician number on claims submitted to the Agency.

Providers are reminded that any pharmacy claim with an incorrect prescribing physician number is subject to recoupment. Pharmacies with repeated violations will be subject to revocation of their Medicaid provider agreement, and referral to federal or state law enforcement personnel for criminal prosecution.