



# ALABAMA MEDICAID PHARMACIST

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A Service of Alabama Medicaid

## PDL Update

Effective July 1, 2008, the Alabama Medicaid Agency updated the Preferred Drug List (PDL) to reflect the recent Pharmacy and Therapeutics (P&T) Committee recommendations as well as quarterly updates. The updates are listed below:

PDL Additions	PDL Deletions*
Veramyst - Intranasal Corticosteroids	Pronestyl SR - Antiarrhythmics
Beconase AQ - Intranasal Corticosteroids	Isordil - Nitrates/Nitrites
Nasacort AQ - Intranasal Corticosteroids	Nitrostat - Nitrates/Nitrites
Optivar - Antiallergic Agents	
Symbicort - Respiratory Agents	

\*denotes that these products will no longer be preferred but are still covered by Alabama Medicaid and will need Prior Authorization (PA).

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The PA request form and criteria booklet, as well as a link for a PA request form that can be completed and submitted electronically, can be found on the Agency website ([www.medicaid.alabama.gov](http://www.medicaid.alabama.gov)).

### HID Help Desk

Monday–Friday

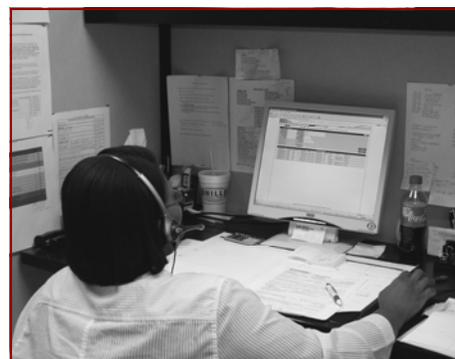
8am–7pm

Saturday

10am– 2pm

Hard copy PA requests may be faxed or mailed to:

Health Information Designs (HID)  
Medicaid Pharmacy Administrative Services  
PO Box 3210  
Auburn, AL 36832-3210  
Fax 800-748-0116  
Phone 800-748-0130



## Drugs of Abuse

According to the Food and Drug Administration (FDA) and the federal Substance Abuse and Mental Health Services Administration (SAMHSA), the abuse of over-the-counter and prescription medication can be just as harmful as the abuse of illegal street drugs. A 2006 study at the University of Michigan confirmed that teen use of prescription drugs for non-medicinal purposes remains

steady, although teen use of street drugs and

**Seroquel® (quetiapine) should be prescribed with caution in patients with a history of substance abuse.**

alcohol is on the decline. The study was also able to corroborate that Oxycontin®, Vicodin®, and cough/cold medications were among the most commonly abused drugs by teens as young as 13.

The Office of Diversion Control (a division of the Drug Enforcement Agency and the U.S. Department of Justice) publishes a list of drugs/chemicals of concern. Some of the prescription drugs included in this list are:

- Benzodiazepines
- Buprenorphine (Suboxone®/Subutex®)
- Carisoprodol (Soma®)
- Cyclobenzaprine (Flexeril®)
- Dextromethorphan
- Fentanyl (Actiq®/Duragesic®)
- Human Growth Hormone
- Hydrocodone
- Hydromorphone (Dilaudid®)
- Methadone
- Methylphenidate
- Oxycodone

In addition, authorities have seen increasing abuse/misuse of Seroquel® (quetiapine). Seroquel® is classified as an atypical antipsychotic and is not a controlled substance; however, officials have reported intranasal, oral, and intravenous use. Some of the first documented incidents took place at the Los Angeles County Jail. It was noted that almost one-third of inmates were feigning psychiatric symptoms to obtain Seroquel® to use or sell. Seroquel® diversion does not only occur in institutional settings. Street names for quetiapine include “quell”, “baby heroin”, “Susie-Q”, and “Q-ball” when mixed with cocaine. Because Seroquel® is not commonly thought of as a particularly ‘addicting’ drug and is sometimes prescribed off-label for sleep, it is relatively easy to obtain and refill without suspicion.

It is now thought that quetiapine should be prescribed with caution in patients with a history of substance abuse and that these patients or patients in high-risk settings should consider alternative medications. Patients that misuse quetiapine are at risk for arrhythmias (potentially fatal), hypotension, weight gain, and diabetes.

### References:

1. Drugs and Chemicals of Concern. Office of Diversion Control. Accessed at [www.deadiversion.usdoj.gov](http://www.deadiversion.usdoj.gov). May 2008.
2. Quetiapine (Seroquel®) abuse. Pharmacist’s Letter/Prescriber’s Letter 2007;23(10):231008.
3. Pinta ER, Taylor RE. Quetiapine addiction? Am J Psychiatry 2007;164:174-5.
4. Seroquel® [prescribing information]. Wilmington, DE: AstraZeneca Pharmaceuticals LP; May 2008.
5. Morin AK. Possible intranasal quetiapine misuse. Am J Health Syst Pharm. 2007 Apr 1;64(7):723-5.
6. Teen abuse of medicinal drugs. FDA Consumer health Information. Accessed at [www.fda.gov/consumer/updates/antidrug071807.html](http://www.fda.gov/consumer/updates/antidrug071807.html). May 2008.

## MedWatch

The MedWatch program was created by the FDA in 1993 to encourage healthcare providers to voluntarily report serious adverse events. The two goals of the program are to educate healthcare providers about the importance of reporting events and to use the information from the reports to provide valuable information back to patients and those in their healthcare neighborhood.<sup>1</sup> MedWatch encourages patients and healthcare providers to report serious adverse events, product quality problems and medication and device use errors.<sup>1</sup>

There are two types of reporting: voluntary and mandatory; each requiring a different form. Both forms can be completed four different ways: online ([www.fda.gov/medwatch](http://www.fda.gov/medwatch)), by phone (1-800-FDA-1088), by fax (1-800-FDA-0178) or by mail after printing an online form which requires no return postage (The FDA Safety Information and Adverse Event Reporting Program, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20852-9787).<sup>2</sup> Voluntary reporting is completed on a FDA 3500 form and may be completed by healthcare professionals, patients and consumers.<sup>3</sup> The mandatory reporting form is FDA 3500A. The 3500A for mandatory reporting is used by investigational and new drug reporters, user facilities personnel, manufacturers, importers and distributors.<sup>4</sup>

Reports are evaluated on a case by case basis by a pharmacist, nurse or physician and then added to a database.<sup>1</sup> The FDA uses this information to determine any needed action. The outcome depends on the type of report, the amount of reports received on the same problem and the gravity of information in the reports. Adverse events may be handled by boxed warnings or product withdrawal, while medication and device use errors could require label changes or instruction modifications.<sup>1</sup> MedWatch then sends the information back to their website, through professional partners like the American Society of Health Systems Pharmacists and through their list serve communication called E-list (join by clicking link on MedWatch homepage).<sup>1</sup>

### Resources:

1. Center for Drug Evaluation and Research. Online Training Seminar. FDA MedWatch and Patient Safety Transcript. <http://www.connectlive.com/events/fdamedwatch/transcript.html> (Accessed on 23 May 2008).
2. US Food and Drug Administration. MedWatch. <http://www.fda.gov/medwatch> (Accessed on 23 May 2008).
3. MedWatch. FDA 3500 Voluntary Reporting Form. [http://www.fda.gov/medwatch/safety/FDA-3500\\_fillable.pdf](http://www.fda.gov/medwatch/safety/FDA-3500_fillable.pdf) (Accessed on 23 May 2008).
4. MedWatch. FDA 3500A Mandatory Reporting Form. [http://www.fda.gov/medwatch/safety/FDA-3500A\\_fillable.pdf](http://www.fda.gov/medwatch/safety/FDA-3500A_fillable.pdf) (Accessed on 23 May 2008).

### MedWatch Reporting

1. Online: [www.fda.gov/medwatch](http://www.fda.gov/medwatch)
2. Phone: 1-800-332-1088
3. Fax: 1-800-332-0178

4. Mail: Print form online and mail to:  
 FDA Safety Information & Adverse Event Reporting Program  
 Food and Drug Administration  
 5600 Fishers Lane  
 Rockville, MD 20852-9787

## Current Treatment Guidelines for Hyperlipidemia

The decision to treat hyperlipidemia generally follows the treatment guidelines of the Third Report of the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III, published in 2002 and updated in 2004. The report stresses that the intensity of treatment should be directed by the degree of cardiovascular risk. Because LDL-C is the major atherogenic lipid component, NCEP-ATP III focuses primarily on achieving target LDL-C levels. For most patients who are prescribed a statin, the target is <130 mg/dL or <100 mg/dL. In ATP-III, patients who have type 2 diabetes without CHD peripheral or carotid vascular disease and patients who have multiple risk factors and a 10-year risk of CHD > 20% are said to have 'CHD equivalents.' This means that the criteria for using drug therapy and the LDL-C target is the same for patients who have a history of CHD.

The 2006 update of the American Heart Association/American College of Cardiology consensus statement on secondary prevention states that an LDL-C goal of <70 mg/dL for high risk patients is a therapeutic option.

[Factors that place patients in the category of very high risk are the presence of established CVD plus 1) multiple major risk factors (especially diabetes), 2) severe and poorly controlled risk factors (especially continued smoking), 3) multiple risk factors of the metabolic syndrome (especially high triglycerides >200 mg/dL plus non-HDL-C >130 mg/dL with low HDL-C <40 mg/dL) and 4) patients with acute coronary syndromes.] If it is not possible to attain LDL-C <70 mg/dL because of a high baseline LDL-C, it generally is possible to achieve LDL-C reductions of >50% with either statins or LDL-C lowering drug combinations. The optional goal of <70 mg/dL does not apply to individuals who are not at high risk.

*Continued, next page.*

**Table 2. NCEP Treatment Guidelines: LDL-C Goals and Cutpoints for TLC and Pharmacotherapy**

Risk Category	LDL Goal	LDL Level to Initiate TLC	LDL Level at Which to Consider Drug Therapy
CHD or CHD Risk Equivalent (10-year risk > 20%)	< 100 mg/dL	≥ 100 mg/dL	≥ 130 mg/dL (100-129 mg/dL, drug optional)*
2 or more Risk Factors (10-year risk ≤ 20%)	< 130 mg/dL	≥ 130 mg/dL	≥ 130 mg/dL (for 10-year risk 10-20%) > 160 mg/dL (for 10-year risk < 10%)
0-1 Risk Factors	< 160 mg/dL	≥ 160 mg/dL	≥ 190 mg/dL (160-189 mg/dL, drug optional)**

\*Some authorities recommend use of LDL-C lowering drugs in this category if an LDL-C < 100 mg/dL cannot be achieved by TLC. Clinical judgment may also call for deferring drug therapy in this category.

\*\*Factors that favor drug therapy after 3 months of TLC include a severe single risk factor (heavy smoking, poorly controlled hypertension, strong family history of premature CHD, or very low HDL-C), multiple life-habit risk factors and emerging risk factors, or 10-year risk approaching 10%.

## Current Treatment Guidelines for Hyperlipidemia (cont'd)

The American College of Cardiology recommends achieving targets for levels of LDL and HDL cholesterol (or of the ratio of total cholesterol to HDL cholesterol) with the use of statins plus drugs that have shown clinical benefits when added to statins (e.g., nicotinic acid, fibrates, and bile acid sequestrants), as tolerated. Efforts should also be made at dietary control and regular exercise. The ACC also notes that conclusions regarding the ENHANCE trial (Vytorin vs Simvastatin) can not be made until clinical-outcome trials are presented within the next two to three years.

### References:

1. Third Report of the National Cholesterol Education Program (NCEP) Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III). Available at [www.nhlbi.nih.gov/guidelines/cholesterol/index](http://www.nhlbi.nih.gov/guidelines/cholesterol/index). Accessed December 2007.
2. Wolters Kluwer Health, Inc, ed. Drug Facts & Comparisons. St. Louis, MO. 2005.
3. ACC Statement on Enhance Trial. Available at [222.acc.org/enhance.htm](http://222.acc.org/enhance.htm). Accessed April 2008.
4. Helfand, Mark, Carson, Susan, Kelley, Cathy. Drug Class Review on HMG-CoA Reductase Inhibitors (Statins). 2006. Accessed December 2007. <http://www.ohsu.edu/drugeffectiveness/reports/final.cfm>.
5. Effects of a tablet splitting program in patients taking HMG-CoA reductase inhibitors: analysis of clinical effects, patient satisfaction, compliance, and cost avoidance. J Manag Care Pharm. 2002 Nov-Dec;8(6):453-8. Accessed online at [www.ncbi.nlm.nih.gov/pubmed/14613379](http://www.ncbi.nlm.nih.gov/pubmed/14613379).

## Helpful Information for Submitting Compound Claims

- The new InterChange system allows for up to 25 NDCs (ingredients) to be sent per claim.
- The claim will be rejected if one or more NDCs are non-covered. For compound claims with one or more non-covered ingredients, a value of "8" should be submitted in the **Submission Clarification Code** field to allow for payment of the remaining covered NDCs.
- For a transaction to be considered a compound claim the compound segment must be sent and the **compound code field** must have a value of "2". A value of "1" in this field indicates that the claim is NOT a compound, in other words, a regular pharmacy claim.
- If the compound code indicates that it is a compound claim, but the compound segment (eg – list of different ingredients) is not sent, the transaction will reject for a syntax error. The quantity for each ingredient billed must be billed at the compound segment level.
- Compounding time (NDC 9999999999) is only payable on a compound claim, not a regular pharmacy claim. A prior authorization (PA) must be on file for the compounding time NDC to be payable. The provider must contact Health Information Designs (HID) at 1-800-748-0130 for compounding time PA information.
- Two NDCs that require PA (for example, compounding time and omeprazole) can, and must, be billed on the same prescription. The InterChange system will search for and apply the appropriate PA to each NDC that requires a prior authorization when it is billed.
- Compound claims typically contain more than one ingredient. If only one ingredient needs to be billed, most likely it does not need to be billed as a compound claim.
- Compounds are priced as follows: each payable ingredient's reimbursement amount is calculated during processing. These amounts are summed, and any TPL and/or copay amounts are applied to this summed amount, which becomes the paid amount on the claim. Only one dispensing fee will be applied to a compound claim.

## DAW-1 Edit

Effective May 1, 2008 a new edit was put in place by Alabama Medicaid. Brand name medications with an available generic equivalent now require an override. The provider must include medical justification for use of the brand name medication and a MedWatch Form 3500 must be completed and sent in with the override request form. HID will forward completed MedWatch forms to the FDA so that issues relating to quality, authenticity, performance, and safety of the medication can be documented. Providers requesting a renewal will not be required to fill out a second MedWatch form.

The following drugs will be EXCLUDED from the edit:

Carbamazepine

Levothyroxine

Pancreatic enzymes

Phenytoin

Warfarin

Digoxin (pending the Class I drug recall)

**An updated override form and the MedWatch form can be found on the Alabama Medicaid website ([www.medicaid.alabama.gov](http://www.medicaid.alabama.gov)) or on the HID website ([www.hidmedicaid.com](http://www.hidmedicaid.com)).**