



# ALABAMA MEDICAID PHARMACIST

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A Service of Alabama Medicaid

## PDL Update

Effective April 1, 2013, the Alabama Medicaid Agency will update 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*
Levemir—Diabetic Agents/Insulins	

*\*Denotes that these brands will no longer be preferred but are still covered by Alabama Medicaid and will require prior authorization (PA) for payment. Available covered generic equivalents (unless otherwise specified) will remain preferred.*

The HID Help Desk is open Monday–Friday from 8am to 7pm and on Saturdays 10am to 2pm. If you need a form, wish to review criteria or have other questions, please access our website at [hidmedicaid.hidinc.com](http://hidmedicaid.hidinc.com) or the Agency website at [medicaid.alabama.gov](http://medicaid.alabama.gov).

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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.



## New Recommendation for BP Control in Diabetic Patients

In a recently published supplement to the American Diabetes Association's (ADA) guideline for the treatment of diabetes, ADA has modified the recommendations for target blood pressure. The new target is now <140/80 mmHg, which has a higher systolic goal than the previous goal of <130/80 mmHg. This change is based on results from the ACCORD trial, which was published in 2010.

An arm of the ACCORD trial tested whether a systolic blood pressure goal of <120 mmHg (intensive therapy) was more beneficial than 130-140 mmHg (standard therapy) in preventing non-fatal MI, non-fatal stroke, and CVD death. Of these primary endpoints, there were no statistically different results (P=0.20). Of their secondary outcomes, only stroke in the intensive group had a statistically significant difference when compared to standard therapy. The blood pressures achieved by both groups was 119/64 mmHg and 133/70 mmHg for the intensive and standard group, respectively. The patients in the intensive therapy group required 3.4 medications in order to reach this goal, while the standard group needed only 2.1 medications. Additionally, the patients in the intensive group demonstrated a higher rate of adverse events due to the hypertensive therapy (eg. syncope, hyperkalemia) at a rate of 3.3% vs 1.1% (P=0.001). Also noted was the fact that over a 5-year period, there was no difference between the intensive and standard therapy in regards to renal function and development of microvascularization problems.

ADA continues to stress that control of blood pressure is paramount in the treatment of diabetes. Many studies have demonstrated the benefits of controlling a diabetic patient's blood pressure to <140 mmHg.

The new supplement also suggests patients who should still try to achieve a systolic blood pressure <130 mmHg. Patients who already have their blood pressure controlled at <130 mmHg with no side effects should continue their current regimen. Younger diabetic patients are also mentioned. The younger patients stand to benefit the most from a long-term antihypertensive therapy in areas such as preventing macro- and microvascular complications. Additionally, patients with a higher risk for stroke should also aim for <130 mmHg.

These new recommendations allow for a slightly more relaxed goal when it comes to treating hypertension in a diabetic patient. The ACCORD trial demonstrated a relative lack of superiority of the old goal of <130 mmHg in attempting to prevent CVD and also a higher rate of adverse events in this group.

### References

American Diabetes Association. Standards of medical care in diabetes-2013. *Diabetes Care* 2013;36(Suppl 1):S11-66. Available from: [http://care.diabetesjournals.org/content/36/Supplement\\_1/S11.full#sec-29](http://care.diabetesjournals.org/content/36/Supplement_1/S11.full#sec-29).

Cushman WC, Evans GW, Byington RP, et al.; ACCORD Study Group. Effects of intensive blood-pressure control in type 2 diabetes mellitus. *N Engl J Med* 2010;362:1575-1585.

## Re-scheduling Hydrocodone Containing Products

In January, an expert panel for the FDA **recommended** that the FDA reschedule all hydrocodone containing products as Schedule II. Currently, hydrocodone products are classified as Schedule III, meaning that patients are currently allowed five refills over a six month period. If hydrocodone was moved to a Schedule II, no refills would be allowed, requiring patients to see their physicians more often. Today, prescription medications account for three-fourths of all drug overdoses.

Hydrocodone containing products include medications such as: Lortab<sup>®</sup>, Vicodin<sup>®</sup>, Norco<sup>®</sup>, Vicoprofen<sup>®</sup>, and Tussionex<sup>®</sup>. Hydrocodone is used to treat pain and also as a cough suppressant.

Hydrocodone has been the most prescribed medication in the United States for many years. In 2012, Alabama ranked 6th in the nation in prescriptions with hydrocodone containing products.<sup>1</sup>

Even though the FDA has **not** actually rescheduled hydrocodone, one state is already making the change. Effective February 23, 2013, New York State moved hydrocodone containing products from Schedule III to Schedule II.<sup>2</sup>

### Examples of Scheduled Medications (list not all inclusive)

Schedule II	Schedule III	Schedule IV	Schedule V
Oxycontin <sup>®</sup>	Lortab <sup>®</sup>	Klonopin <sup>®</sup>	Lyrica <sup>®</sup>
Methadone	Vicodin <sup>®</sup>	Soma <sup>®</sup>	
Adderall <sup>®</sup>	Norco <sup>®</sup>	Ambien <sup>®</sup>	
Fentanyl Patch	Tussionex <sup>®</sup>	Adipex-P <sup>®</sup>	

### References

FDA website. [www.fda.gov](http://www.fda.gov).

New York State Department of Health. Available from: <http://www.health.ny.gov/professionals/narcotic/>.

## DEA National Prescription Drug Take-Back Day

The DEA has scheduled the National Prescription Drug Take-Back Day for **Saturday, April 27, 2013, from 10:00 am to 2:00 pm**. This is an opportunity for unused, unwanted prescription medications to be disposed of in a safe manner. The DEA has held four previous Take-Back events in conjunction with state, local, and tribal law enforcement partners. Over 1,000 tons of prescription medications have been removed from the public.

Collection sites have not been released at this time. Collection sites should be updated on April 1, 2013. Please visit [http://www.dea diversion.usdoj.gov/drug\\_disposal/takeback/](http://www.dea diversion.usdoj.gov/drug_disposal/takeback/) for more information and to locate a collection site in your area.



## Lower Recommended Zolpidem Doses

In January, the FDA announced it was requiring the manufacturers of zolpidem products to lower current recommended doses. Products affected are marketed as generics and under the brand names Ambien<sup>®</sup>, Ambien CR<sup>®</sup>, Edluar<sup>®</sup>, and Zolpimist<sup>®</sup>. New data show that zolpidem blood levels in some individuals may be high enough to lead to next-morning impairment. Next-morning impairment occurs when patients are awake the morning after taking an insomnia medication, but the levels of the medication in their blood are high enough to impair activities that require alertness.

The FDA received data from driving simulation and laboratory studies that indicated that zolpidem levels above 50 ng/mL were capable of impairing driving to the extent of causing a motor vehicle accident. Pharmacokinetic trials of Ambien<sup>®</sup> 10 mg (or bioequivalent zolpidem products) in 250 women and 250 men found that almost 15% of women and 3% of men had zolpidem concentrations that exceeded 50 ng/mL approximately 8 hours post-dosing. Three women had measurements that were  $\geq 90$  ng/mL at approximately 8 hours post-dosing.

In pharmacokinetic trials of zolpidem extended-release 12.5 mg, approximately 33% of women and 25% of men had zolpidem blood concentrations that exceeded 50 ng/mL almost 8 hours post-dosing. Approximately 5% of patients had blood levels  $\geq 100$  ng/mL. Studies of zolpidem extended-release 6.25 mg revealed 15% of women and 5% of men had zolpidem blood concentrations  $\geq 50$  ng/mL almost 8 hours post-dosing. Pharmacokinetic trials did not demonstrate a relationship between zolpidem blood level and patient's body weight or ethnicity. Zolpidem blood levels can be higher in the elderly and lower doses are already recommended in this population. Interestingly, zolpidem blood levels in elderly patients have not been found to be affected by gender.

Using lower doses of zolpidem results in less drug remaining in the bloodstream in the morning hours. Data indicate that the highest risk for next-morning impairment is for patients taking the extended-release forms of these drugs. Women eliminate zolpidem from their bodies more slowly than men and are at an increased risk of next-morning impairment. The FDA has notified manufacturers that the recommended doses for women should be cut in half for both immediate-release and extended-release products. The FDA has asked manufacturers to change the labeling to recommend physicians and other healthcare providers consider lowering the dose in men.

Drowsiness is a common side effect of medications taken for insomnia. Drug labels of insomnia medications contain warnings that patients may still feel drowsy the day after taking these medications. It is important to remind patients on any insomnia medication that they may feel fully awake the morning after use, but that their mental alertness may be impaired. For zolpidem and other insomnia medications, the lowest dose that treats the patient's symptoms should be prescribed.

The following chart details the current dosing recommendations and the FDA's proposed dosing recommendations for zolpidem immediate-release and zolpidem extended-release products.

## Lower Recommended Zolpidem Doses, continued

### FDA Zolpidem Dosing Recommendations for Non-Elderly Adults

	Dosing recommendations in current drug label for zolpidem	FDA’s proposed new dosing recommendation for zolpidem
Ambien <sup>®</sup> , Edluar <sup>®</sup> , Zolpimist <sup>®</sup>	<b><u>Men and Women:</u></b> 10 mg once daily, immediately before bedtime	<b><u>Women:</u></b> 5 mg once daily, immediately before bedtime <b><u>Men:</u></b> 5 or 10 mg once daily, immediately before bedtime
Ambien CR <sup>®</sup>	<b><u>Men and Women:</u></b> 12.5 mg once daily, immediately before bedtime	<b><u>Women:</u></b> 6.25 mg once daily, immediately before bedtime <b><u>Men:</u></b> 6.25 or 12.5 mg once daily, immediately before bedtime

References

U.S. Food and Drug Administration. (2013). Risk of next-morning impairment after use of insomnia drugs; FDA requires lower recommended doses for certain drugs containing zolpidem (Ambien, Ambien CR, Edluar, and Zolpimist). Available from: <http://www.fda.gov/drugs/drugsafety/ucm334033.htm>.

U.S. Food and Drug Administration. (2013). FDA requiring lower recommended dose for certain sleep drugs containing zolpidem. Available from: <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm334798.htm>.

## Alabama Medicaid Package Size Edit

Effective **April 1, 2013**, Alabama Medicaid will implement a package size edit. This edit will prevent a claim for a medication whose dispensed quantity is not divisible by the drug’s package size from paying. This would only apply to specified drugs that are available in unconventional package sizes. For example, a drug with a package size of 0.4ml/unit would deny if the quantity submitted on the claim was 1 unit. If you receive this edit, please verify the package size of the product being dispensed and resubmit with the correct quantity.

## Alabama Medicaid Updates

### DEA Validation for Controlled Substances

Effective May 13, 2013, Alabama Medicaid will DENY any claim for a controlled drug written by a prescriber who does not have their DEA number registered with the Department of Justice (DOJ) and on file at Medicaid. Medicaid is implementing these changes as a result of a report issued by the Government Accountability Office (GAO).

These edits are designed to prevent controlled substances from being filled when the prescription is written by an unauthorized prescriber. The following edits have been in place since November 2012 and are currently displaying as informational on the provider's remittance advice:

<u>Edit</u>	<u>Description</u>
1038	DEA NOT ON FILE FOR PRESCRIBER
1039	PRESCRIBER DEA NOT EFFECTIVE FOR DATE PRESCRIBED
1040	PRESCRIBER DEA DOES NOT PERMIT DRUG SCHEDULE

*NOTE: The claims which are currently paying and posting one of the informational edits above, will deny effective May 13, 2013.*

**What action needs to be taken to prevent claims from denying on May 13, 2013?**

**Physicians** – Make sure your DEA number is registered with DOJ and is on your enrollment file at Medicaid. **Medicaid deadline for submission: May 1, 2013.**

To confirm if your DEA number is appropriately registered with the DOJ, and to ensure your correct address/contact information is registered with the DOJ, you may call the **Department of Justice Registration Number Toll Free: (888) 514-7302 or (888) 514-8051**. Prescribers of controlled substances are mandated to re-register their DEA license every three years.

To ensure your DEA is on file at Medicaid, fax a copy of the provider's DEA Registration Certificate to Provider Enrollment (fax 334-215-4298) and include the provider's Name, NPI number, and license number on the certificate. Medicaid will apply the DEA to all service locations based on the provider's NPI and license number. **The DEA information should be received by Provider Enrollment prior to May 1, 2013**. This deadline will allow Provider Enrollment time to enter the information in the provider's file before the May 13, 2013, implementation date.

**Pharmacies** – If you are receiving the informational edits, contact the provider who ordered the prescription and advise them to fax a copy of the provider's DEA Registration Certificate to Provider Enrollment (fax 334-215-4298) and include the provider's Name, NPI number, and license number on the certificate.

**Prescribers:** Please take a moment to validate your DEA number information. Medicaid encourages all providers to be proactive and ensure the DEA number of the prescribing provider is registered with the Department of Justice (DOJ) and on file at Medicaid prior to May 1, 2013.