Alabama Medicaid Pharmacist

Published Quarterly by Health Information Designs, Inc., Spring 2009 — A Service of Alabama Medicaid

PDL Update

Effective April 1, 2009, 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*
Aciphex (GI Agents-PPI)	Imitrex (Selective Serotonin Agonist)
Omeprazole (GI Agents-PPI)	Caduet (HMG CoA Reductase Inhibitor)
Treximet (Selective Serotonin Agonist)	Metadate CD (Cerebral Stimulants/ Agents for ADD/ADHD)
Patanase (EENT-Antiallergic)	Pexeva (SSRI)

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

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).

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Reminder

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.

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

HID Help Desk

Monday–Friday

8am–7pm

Saturday

10am– 2pm

New Drug Updates

This quarter saw several new drugs being released.

Trilipix

The first, Trilipix (fenofibric acid, delayed release), is classified as an antihyperlipidemic agent. It is indicated for use:

- in combination with a statin, to reduce triglycerides (TG) and increase HDL-C in patients diagnosed with mixed dyslipidemia and CHD OR a CHD risk equivalent who are on optimal statin therapy to achieve their LDL-C goal, OR
- as monotherapy to reduce TG in patients with severe hypertriglyceridemia, OR
- as monotherapy to reduce elevated LDL-C, total-C, TG, and Apo B, and to increase HDL-C in patients with primary hyperlipidemia or mixed dyslipidemia.

Trilipix should not be used in patients with severe renal dysfunction, active liver disease, gallbladder disease, or nursing mothers. Trilipix may cause myopathy/rhabdomyolyisis, increases in serum transaminase and/or serum creatinine levels, and increased risk of cholelithiasis.

Trilipix should be used with caution in patients taking coumarin anticoagulants, bile acid resins, or cyclosporine.

The most common adverse reactions are: headache, back pain, nasopharyngitis, nausea, myalgia, diarrhea, and upper respiratory tract infection.

Trilipix is available as a 45mg or 135mg capsule and is recommended to be dosed as follows:

- Mixed dyslipidemia – 135mg daily
- Hypertriglyceridemia – 45 to 135mg daily
- Renally impaired patients – 45mg daily
- Maximum recommended dose – 135mg daily
- May be taken without regard to food
- May be taken at the same time as a statin

Reference:

Trilipix™ [prescribing information]. North Chicago, IL: Abbott Laboratories; December 2008.

Banzel

Banzel (rufinamide), is classified as an antiepileptic agent. The exact mechanism by which Banzel exerts its antiepileptic effect is unknown. It is indicated for adjunctive treatment of seizures associated with Lennox-Gastaut syndrome in adults and children ages 4 and older.

Banzel is contraindicated for use in patients with Familial Short QT syndrome. Banzel may cause suicidal ideation and/or behavior in some patients. Other side effects include somnolence, fatigue, coordination abnormalities, dizziness, gait disturbances, and ataxia. Multi-organ hypersensitivity syndrome has been reported in association with Banzel therapy. These reactions occurred mostly in the pediatric population and usually within four weeks of starting Banzel. If a hypersensitivity reaction is suspected, the medication should be discontinued and alternative therapy initiated.

Banzel should be used with caution in patients taking phenytoin or hormonal contraceptives.

Banzel is available as a 200mg or 400mg tablet. Dosing for children should start at a daily dose of approximately 10mg/kg/day given in two equally divided doses. The dose should be increased in 10mg/kg increments every other day until a target dose of 45mg/kg/day OR 3200mg/day (whichever is less) is reached.

Dosing for adults should start at a daily dose of 400-800mg/day given in two equally divided doses. The dose should be increased by 400-800mg/day every two days until a maximum daily dose of 3200mg/day (given in two equally divided doses) is reached.

Banzel can be crushed or divided, and is recommended to be taken with food.

As with all antiepileptic drugs, it is recommended that patients discontinuing Banzel be tapered and monitored by a physician during the tapering process.

Reference:

Banzel™ [prescribing information]. Woodcliff Lake, NJ: Eisai Co.; November 2008.

PrandiMet

PrandiMet (repaglinide and metformin), is an antidiabetic agent. This drug combines repaglinide, which is a meglitinide, and metformin. It is indicated for use in patients with type 2 diabetes who are not controlled on a meglitinide or metformin alone.

PrandiMet should not be used in patients with renal impairment, metabolic acidosis, or patients receiving both gemfibrozil and itraconazole. Side effects include hypoglycemia, headache, and GI disturbances.

As with other metformin products, lactic acidosis can occur, so patients should be warned to report malaise, myalgias, respiratory distress, increased somnolence, and nonspecific abdominal distress.

New Drug Update, Cont'd.

PrandiMet is available in a 1/500mg and 2/500mg tablet. Dosages should be individualized, but it is recommended to start with 1/500mg two times a day and not to exceed 10/2500mg daily. Patient doses should be given 15 minutes before a meal. If a patient skips a meal, the dose for that meal should be skipped as well.

Reference:

PrandiMet™ [prescribing information]. Princeton, NJ: Novo Nordisk; June 2008.

Apriso

Apriso (mesalamine granules) is a new GI drug. It is indicated for maintenance of remission of ulcerative colitis in patients 18 years and older.

Patients with phenylketonuria should be aware that Apriso contains aspartame, equivalent to 0.56 mg of phenylalanine. Common side effects include headache, diarrhea, upper abdominal pain, and nausea.

Apriso is available as a 0.375g capsule. The recommended dose is 4 capsules once daily in the morning. Apriso can be taken with or without food, but should not be taken with antacids.

Reference:

Apriso™ [prescribing information]. Morrisville, NC: Salix Pharmaceuticals; October 2008.

Kapidex

Kapidex (dexlansoprazole) is a new proton pump inhibitor. It is indicated for:

- Healing all grades of erosive esophagitis (EE) for up to 8 weeks
- Maintaining healing of EE for up to 6 months
- Treating heartburn associated with symptomatic non-erosive gastroesophageal reflux disease (GERD) for 4 weeks.

Most commonly reported side effects include diarrhea, abdominal pain, nausea, upper respiratory tract infection, vomiting, and flatulence.

Kapidex should not be given with atazanavir, with drugs for which gastric pH is important for bioavailability, and if given with warfarin, INR/PT should be monitored.

Kapidex is available as a 30mg and 60mg capsule.

When used in the healing of EE, dose should be 60mg daily. When used for the maintenance of healed EE and for symptomatic non-erosive GERD, the dose should by 30mg daily. Kapidex can be taken without regard to meals and should be swallowed whole. If necessary, capsules can be opened, sprinkled on one tablespoon of applesauce, and swallowed immediately.

Reference:

Kapidex™ [prescribing information]. Deerfield, IL: Takeda Pharmaceuticals America, Inc.; January 2009.

Food and Drug Administration (FDA) Warns Consumers of Extortion Plot

In November 2008, the FDA released a warning to consumers about a fraudulent scheme to extort money by callers falsely identifying themselves as "FDA special agents", or other FDA officials.

The FDA reports that the scheme first starts with a call that entices callers to buy discounted prescription drugs by wiring funds to the Dominican Republic. No drugs are ever delivered, but the consumer later receives a call from an "FDA special agent". The "agent" tells the consumer that they have to pay a fine of several thousand dollars in order to avoid incarceration or other legal action for a fictitious violation.

"Impersonating an FDA official is a violation of federal law," said Michael Chappell, the FDA's acting associate commissioner for regulatory affairs. "The public should note that no FDA official will ever contact a consumer by phone demanding money or any other form of payment. FDA officials always present identification in person when conducting official business."

The calls appear to be coming from within the U.S. but are actually either ported voice-over-the-Internet-protocol numbers (calls made directly from a computer and moved or "ported" to other computers to avoid detection) or cellular phones.

The FDA is investigating and complaints or information regarding this scheme should be reported to the FDA Office of Criminal Investigations at (800) 521-5783.

Additional information or inquiries, please dial (888) INFO-FDA.

Reference:

Food and Drug Administration. Press Release: FDA Warns Consumers of Extortion Plot. http://www.fda.gov/bbs/topics/NEWS/2008/NEW01913.html (accessed 2009 Jan 20).

Appropriate Utilization of Dispense As Written Codes

Dispense As Written (DAW) product selection codes are an integral part of accurate billing to the Alabama Medicaid Agency and provide the agency with the reason why a specific brand or generic is dispensed based on the prescriber's instructions. Failure to accurately use DAW codes results in misinformation to the Pharmacy program and its decision making process. Misinformation on claims may also result in retrospective pharmacy review and/or recoupment. Inaccurate usage of DAW codes is among one of the discrepancies found during an audit and is one of the Primary Pharmacy Audit Components listed in the Provider Billing Manual, Section 27.2.5. The following codes are the various DAW codes available to the Alabama Medicaid Pharmacy program with explanations that have been taken from the National Council on Prescription Drug Programs (NCPDP) version 5.1 data dictionary for field 408-D8 Product Selection Codes. Providers should utilize the correct codes based upon the information submitted on the prescription and the prescriber's signature.

Ø=No Product Selection Indicated-This is the field default value that is appropriately used for prescriptions where product selection is not an issue. Examples include prescriptions written for single source brand products and prescriptions using the generic name and a generic product is dispensed.

1=Substitution Not Allowed by Prescriber-This value is used when the prescriber indicates, in a manner specified by prevailing law, that the product is to be Dispensed As Written.

2=Substitution Allowed-Patient Requested Product Dispensed-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the patient requests the brand product. This situation can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources. (Not permitted by Alabama Medicaid)

3=Substitution Allowed-Pharmacist Selected Product Dispensed-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the pharmacist determines that the brand product should be dispensed. This can occur when the prescriber writes the prescription using either the brand or generic name and the product is available from multiple sources.

4=Substitution Allowed-Generic Drug Not in Stock-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the brand product is dispensed since a currently marketed generic is not stocked in the pharmacy. This situation exists due to the buying habits of the pharmacist, not because of the unavailability of the generic product in the marketplace.

5=Substitution Allowed-Brand Drug Dispensed as a Generic-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the pharmacist is utilizing the brand product as the generic entity.

6=Override (Not permitted by Alabama Medicaid)

7=Substitution Not Allowed-Brand Drug Mandated by Law-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted but prevailing law or regulation prohibits the substitution of a brand product even though generic versions of the product may be available in the marketplace.

8=Substitution Allowed-Generic Drug Not Available in Marketplace-This value is used when the prescriber has indicated, in a manner specified by prevailing law, that generic substitution is permitted and the brand product is dispensed since the generic is not currently manufactured, distributed, or is temporarily unavailable.

9=Other (Not permitted by Alabama Medicaid)

To indicate instructions to the dispensing pharmacy, a physician simply signs the prescription in a manner specified by prevailing law to indicate to a providing pharmacy whether or not generic substitution is allowed. Effective May 1, 2008 an override form and Medwatch 3500 form is required in order to medically justify a provider's reason for requesting a branded product when an exact generic equivalent is available. DAW overrides and the Medwatch 3500 form should be submitted to Health Information Designs.

Hay Fever

Hay fever (allergic rhinitis) is most common in the spring when plants begin pollinating. Patients with allergies commonly complain of runny or stuffy nose, sneezing, and/or itchy throat and eyes. The symptoms can be moderate to severe, with some cases progressing to chronic sinusitis or asthma.

Fortunately, these symptoms are easily treated. Patients have access to non-sedating over-the-counter antihistamines, allergy eye drops, and physician-prescribed intranasal corticosteroids. It is recommended that these patients use air conditioning and air purifying devices, and wear masks for outdoor work.

Listed below are examples of Alabama Medicaid products available without a prior authorization indicated for use in the treatment of allergic rhinitis:

Antiallergic Agents:

Optivar, Pataday, Patanase, Patanol, Nasalcrom OTC, Zaditor OTC, and Cromolyn Sodium.

Intranasal Corticosteroids:

Beconase AQ, Nasacort AQ, Nasonex, Veramyst, Fluticasone, and Flunisolide.

Oral Antihistamines:

Brompheniramine, Cetirizine, Chlorpheniramine, Clarinex, Clemastine, Diphenhydramine, Fexofenadine, Loratadine, and Triprolidine.

Vasoconstrictors:

Tyzine, Naphazoline, and Phenylephrine

References:

American Lung Association. Facts About Hay Fever. www.lungusa.org (accessed 2009 February 10).

American Academy of Allergy, Asthma, and Immunology. Allergic Rhinitis. www.aaaai.org (accessed 2009 February 10).

Treating Hypertension

In 2007, the American Heart Association (AHA) released new guidelines for the treatment of hypertension. For primary prevention of coronary artery disease (CAD), it is recommended that patients are treated to a blood pressure of < 140/90 mmHg. For patients with CAD, CAD equivalents, and high risk for CAD, the AHA recommends treatment to a goal of < 130/80 mmHg. This more aggressive goal is also recommended for patients with diabetes and chronic kidney disease.

It is important to treat patients with additional risk factors more aggressively, because studies have shown a significant causal link between increases in blood pressure and overall cardiovascular disease and all-cause mortality.

According to the National Health and Nutrition Examination Survey (NHANES), there are roughly 50 million people in the United States that have high blood pressure requiring treatment. Approximately 2/3 of these patients are not controlled on one drug, and require the use of 2 or more drugs.

For many years, a thiazide diuretic has been recommended as first-line therapy in patients without complications. Thiazides are also commonly used as add-on therapy for patients not meeting their treatment goals. However, now that there are more treatment options (such as ARBs, CCBs, and ACEIS), experts feel that more information is needed on the most appropriate first-line medication choices for patients. The ACCOMPLISH trial compared the cardiovascular outcomes in high-risk patients when treated with an ACE inhibitor and a calcium channel blocker (AC group) versus patients treated with an ACE inhibitor and a thiazide (AT group).

The ACCOMPLISH trial started in 2003. 11,000 patients with hypertension plus a history of cardiovascular events, kidney disease, peripheral artery disease, left ventricular hypertrophy, or diabetes were enrolled and randomized into two groups. Target blood pressure for

ACCOMPLISH Trial, Cont'd.

patients was < 140/90 mmHg and < 130/80 mmHg for patients with diabetes or kidney disease. The primary outcome measure was time to first cardiovascular event and secondary outcome measure was a composite of cardiovascular death, stroke, and heart attack.

The study was stopped after 36 months when it was determined that the difference between groups exceeded a predetermined level. The information from the study is listed below:

- The primary outcome occurred in 9.6% of the AC group and in 11.8% of the AT group ($p<0.001$).
- The secondary outcome occurred in 8.6% of the AC group and 10.3% of the AT group ($p=0.002$).
- Mean blood pressure was similar between the two groups, 131.6/73.3 mmHg in the AC group and 132.5/74.4 mmHg in the AT group.
- Peripheral edema occurred in 31.2% of the AC group and in 13.4% of the AT group.
- For the primary endpoint, 1 person benefited for every 46 patients treated over 3 years. (NNT/3years = 46)

The conclusion is that the ACE inhibitor-CCB combination was superior to the ACE inhibitor-thiazide combination in reducing blood pressure and cardiovascular events in patients with a high risk profile. The reasons for the differences in outcomes are not yet clear.

References:

1. Jamerson K, Weber MA, Bakris GL, et al. Benazepril plus amlodipine or hydrochlorothiazide for hypertension in high-risk patients. N Engl J Med 2008;359:2417-28.
2. ACEI plus calcium channel blocker or hydrochlorothiazide for hypertension: the ACCOMPLISH trial. Pharmacist's Letter/Prescriber's Letter 2009;25(1):250105.
3. National Heart, Lung, and Blood Institute. The Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC 7). Available at www. nhlbi.nih.gov/guidelines/hypertension/jnc7full.pdf (accessed 2009 January 20).
4. National Center for Health Statistics – National Health and Nutrition Examination Survey (NHANES). www.cdc.gov/nchs/nhanes (accessed 2009 January 20).

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