



ALABAMA MEDICAID PHARMACIST

Published Quarterly by Health Information Designs, LLC, Winter 2014 edition

A Service of Alabama Medicaid

PDL Update

Effective January 1, 2014, 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*
Pulmicort—Respiratory/Orally Inhaled Corticosteroids	Budesonide—Respiratory/Orally Inhaled Corticosteroids

**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 or the Agency website at 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.



Guidelines for the Diagnosis and Management of GERD

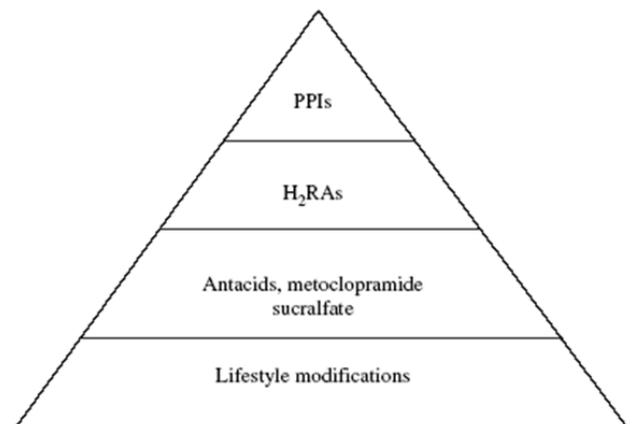
In March 2013, the American College of Gastroenterology (ACG) published new guidelines for the diagnosis and management of gastroesophageal reflux disease (GERD). GERD is defined as “a condition which develops when the reflex of the stomach contents causes troublesome symptoms and/or complications.” Overall, the new guidelines include nine recommendations for establishing the diagnosis of GERD, about a dozen for managing GERD, six points outlining the surgical options for GERD, five potential risks associated with PPIs, seven points regarding extraesophageal presentations of GERD, six recommendations for managing GERD refractory to treatment with PPIs, and eight notes regarding complications associated with GERD.

GERD is diagnosed based on signs, symptoms (such as heartburn, acid regurgitation, difficulty swallowing), history, and physical exam. Occasionally, the doctor may order a diagnostic test or study to help in the diagnosis, such as a barium swallow, an upper GI endoscopy, blood count, blood chemistry, and an EKG to rule out a heart problem. The current guidelines emphasize that an endoscopy is not required to establish a diagnosis of GERD. Symptoms in GERD are very specific and easy to establish, and in the absence of alarm features (trouble swallowing, painful swallowing, unexplained weight-loss, vomiting blood, blood in stool), endoscopies are too invasive and unnecessary for many patients. Too many patients are still referred for endoscopy for the diagnosis of GERD.

In previous guidelines, weight loss has always been a strong recommendation, but there was never much supporting literature to back the recommendation. The new guidelines contain evidence from a cohort study from Norway called the HUNT study, which looked at more than 100,000 patients in a patient cohort analysis. They found that a body mass index (BMI) reduction of 3.5 units resulted in a less likelihood of reporting GERD symptoms or using GERD-related medications.

Other non-pharmacological recommendations remained consistent, such as avoiding meals 2-3 hours prior to bedtime, along with raising the head of the bed to help prevent nighttime GERD symptoms. Patients do not necessarily need to eliminate, but should try to reduce, foods that can trigger reflux (including chocolate, caffeine, alcohol, acidic and/or spicy foods).

Uncomplicated GERD therapy is initiated based mainly upon the patient's history including response to previous GERD therapy. Depending upon the initial therapy used, the medical regimen is adjusted using a step-up or step-down approach with the goal of identifying the least potent, but still effective, regimen. The step-up approach starts with as needed over-the-counter antacids (for example, calcium carbonate) and/or H₂ receptor blockers (for example, ranitidine), then moves up to prescription H₂-blockers (twice daily), and finally to intermittent (2 weeks) use of a PPI, which can move up by dosage, frequency, and duration based upon results of the 2 week trial. To get off of long term therapy, the same order but in reverse (a step-down manner) can be used.



Guidelines for the Diagnosis and Management of GERD

In terms of pharmacological management, the new guidelines try to strike a balance between the risks and benefits of the use of PPIs for GERD. PPIs are still the gold standard for treating patients with GERD, despite some possible drawbacks which are mentioned. There are currently seven available PPIs, including three that can be obtained over-the-counter. Meta-analyses fail to show a significant difference in efficacy for symptom relief among PPIs. PPI therapy should be initiated at once a day dosing, 30-60 minutes before the first meal of the day for maximal pH control, although newer PPIs may offer dosing flexibility relative to meal timing. According to the guidelines, the newest agent, dexlansoprazole (FDA approved in 2009), appears to have similar efficacy in pH control regardless of meal timing.

If a patient has a partial response to once daily therapy, then therapy should be tailored with an adjustment of dose timing and/or twice daily dosing should be considered in patients with night-time symptoms, variable schedules, and/or sleep disturbance.

Since the last guidelines, there have been multiple concerns regarding the long-term safety of PPIs. The US Food and Drug Administration made a label change on PPIs, saying that the loss of bone density has been described. The odds ratios for hip fracture, wrist fracture, and cervical spine fracture were increased in PPI users. There does not appear to be an increased risk of osteoporosis, except in patients with other risk factors for hip fracture. The committee decided, on the basis of the weighted evidence, to make a strong recommendation that PPI use is not contraindicated in patients with bone density loss.

Also there is an ongoing concern about the relationship between PPI therapy and infectious diseases. The problem with acid suppression therapy for extended periods is that the therapy is also suppressing the acid's ability to act as one of the body's natural barriers against infectious organisms. Therefore, a higher risk of certain infections was noticed. PPI use does not appear to be a definitive risk factor yet for the development of *Clostridium difficile* (*C. diff*) infection but should be considered as a factor in all patients at risk and on PPIs. The guidelines committee also suggested that the evidence for community-acquired pneumonia (CAP) was there, but only in the short term use. Extended duration of exposure to PPIs had no effect on repetitive pneumonia and that PPIs cannot be established as the determining risk factor for it still.

In summary, there is now more supporting evidence for previous recommendations including a reduction in ordering endoscopies, the promotion of weight loss, the use of PPIs in osteoporosis patients, the relationship between PPIs and *C. Diff* and CAP infections, and promise of newer agents in relation to meal time dosing interference. There are still many more circumstantial specific recommendations that relate to the diagnosis and treatment of GERD and GERD-related complications, including surgical management, that are not discussed in this article. For more information please refer to the 2013 ACG guidelines.

References:

Katz PO, Gerson LB, Vela MF. Guidelines for the diagnosis and management of gastroesophageal reflux disease. *Am J Gastroenterol* 2013; 108:308.

Follow-up on OTC Cough and Cold Product Withdrawal

A recent *Pediatrics* study published on November 11, 2013 examined the 2007 manufacturer withdrawal of OTC infant cough and cold medications, and the subsequent label changes in 2008 to < 4 years old, to see if it had an impact on emergency department visits in children in relation to adverse drug events. This withdrawal, and later label change, was done in response to mounting evidence that suggested OTC cough and cold medications were no more effective than placebos in young children, and actually linked these medications with increased emergency room visits as a result of adverse effects. The study found that since 2007, there was an overall decline in emergency room visits by children <3 years old as a result of OTC cough and cold medication adverse drug events relative to other drugs. To be more specific, before the withdrawal of the infant cough and cold medications, children under age 2 accounted for 4.1 percent of all emergency visits for adverse drug events; after the market withdrawal, they accounted for only 2.4 percent of such visits (a 41% decrease). In addition, among children ages 2 to 3, emergency visits for adverse drug events decreased from 9.5 percent of all adverse drug visits, to 6.5 percent (a 32% decrease) following the label change.

Interestingly, the study also took a look at whether or not these emergency room visits were the result of supervised or unsupervised ingestion of OTC cough and cold medications. As expected, unsupervised ingestions accounted for 64.3% of emergency room visits involving children <2 years old and 88.8% of visits involving children aged 2 to 3 years, after the withdrawal and labeling revision. This further highlights the importance of child-resistant packaging and keeping these medications out of the reach of children.

Alabama Medicaid PDL Available through Epocrates

Providers can access Alabama Medicaid's Preferred Drug List (PDL) using the Epocrates® drug reference software on their mobile device (iPhone, iPod Touch, iPad, Android, and BlackBerry) or an Internet-connected computer. By downloading the Epocrates application to a mobile device or through the Internet, providers can check preferred drug status, prior authorization requirements, drug alternatives, generic substitutes, and quantity limits.

Additionally, the software features a drug reference that includes information such as indication, dosing, contraindications, drug interactions and adverse reactions. The PDL and drug reference are available at www.epocrates.com.

How to Add the Alabama Medicaid PDL in Epocrates

1. Go to www.epocrates.com.
2. Click **My Account** at the top right of the page.
3. Enter your email address and password and click **Sign In**. (If you do not have an account, click **Register Now** to create one.)
4. Click **Edit Formularies**.
5. For **State**, choose "Alabama"; for **Category**, choose "Health Plans."
6. Select and add the Alabama Medicaid formulary, and click **Done** when you are finished.
7. Update your Epocrates mobile application, and the formularies on your mobile device will be changed accordingly.

For more detailed instructions or assistance with a forgotten user name (email) and password, contact customer support at goldsupport@epocrates.com or call 1-800-230-2150.

January 1st Pharmacy Changes

Effective January 1, 2014, the Alabama Medicaid Agency will:

1. **Limit the number of outpatient pharmacy prescriptions to five total drugs (including up to four brands) per month for adults.** *Children under 21 and nursing home recipients are excluded.* Allowances will be made for up to five additional (10 total) prescriptions for brand and generic antipsychotics, antiretrovirals, and anti-epileptic drugs. In no case can total prescriptions exceed 10 per month per recipient.
2. **Implement a mandatory three-month maintenance supply program for selected medication classes.** A maintenance supply prescription will only be counted towards the prescription limit in the month in which it is filled, and will be required after 60 days stable therapy. The selected classes include:

Medication Class	Medications Included
ACE Inhibitors	Preferred generics and brands
Antidepressants	Preferred generics and brands
Angiotensin II Receptor Blockers	Preferred generics and brands
Asthma	Generic montelukast
Beta Blockers	Preferred generics and brands
Calcium Channel Blockers	Preferred generics and brands
Cardiotonic Agents	Generic digoxin
Contraceptives	Oral, vaginal rings, patches only
Diabetic Agents/Supplies	Generic metformin, generic sulfonylureas, OTC
Direct Vasodilators	Generic hydralazine
Diuretics	Preferred generics and brands (now includes
Estrogens	Generic estradiol tablets
Lithium	All covered products
Men's Health	Generic tamsulosin
Potassium Chloride	Generic potassium chloride
Statins	Preferred generics and brands
Platelet Aggregation Inhibitors	Generic clopidogrel
Thyroid Replacement	All covered products

January 1st Pharmacy Changes, continued

3. Reimburse for agents used to promote smoking cessation in accordance with mandatory coverage required under the Affordable Care Act. These agents will require prior authorization and the recipient must enroll in the Alabama Department of Public Health Quitline. More information can be found at www.medicaid.alabama.gov under the Pharmacy/DME page.
4. Cover benzodiazepines and barbiturates (under the PDL) for eligible recipients.
5. Require prior authorization for payment of generic budesonide (Pulmicort). Brand Pulmicort Respules will be preferred with no PA.

Note: Use Dispense as Written (DAW) Code of 9 for brand Pulmicort Respules. DAW Code of 9 indicates the following: Substitution Allowed by Prescriber but Plan Requests Brand - Patient's Plan Requested Brand Product to be Dispensed.

6. Update the Preferred Drug List (PDL) to reflect the recent Pharmacy and Therapeutics (P&T) Committee's recommendations as well as quarterly updates. The updates are listed below:

PDL Additions	
Pulmicort	Respiratory/Orally Inhaled Corticosteroids
PDL Deletions	
budesonide (generic Pulmicort)	Respiratory/Orally Inhaled Corticosteroids

For additional PDL and coverage information, visit our drug look-up site at <https://www.medicaid.alabamaservices.org/ALPortal/NDC%20Look%20Up/tabId/39/Default.aspx>.



The PA request form and criteria booklet, as well as a link for a PA request form that can be completed and submitted electronically online, can be found on the Agency's website at www.medicaid.alabama.gov and should be utilized by the prescribing physician or the dispensing pharmacy when requesting a PA. Providers requesting PAs by mail or fax should send requests to:

Health Information Designs (HID)
Medicaid Pharmacy Administrative Services
 P. O. Box 3210 Auburn, AL 36832-3210
 Fax: 1-800-748-0116
 Phone: 1-800-748-0130

Incomplete PA requests or those failing to meet Medicaid criteria will be denied. If the prescribing physician believes medical justification should be considered, the physician must document this on the form or submit a written letter of medical justification along with the prior authorization form to HID. Additional information may be requested. Staff physicians will review this information.

Policy questions concerning this provider notice should be directed to the Pharmacy Program at (334) 242-5050. Questions regarding prior authorization procedures should be directed to the HID help desk at 1-800-748-0130.